

THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

THE UNITED STATES OF) No. H-07-CR-362
AMERICA)
) HOUSTON, TEXAS
-vs-) JULY 2, 2008
)
KEVIN XU) 8:32 a.m.

Volume III

TRANSCRIPT OF JURY TRIAL
BEFORE THE HONORABLE SIM LAKE AND A JURY

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1 (Outside the presence of the jury.)

2 THE COURT: You wanted to take up something before
3 the jury came in.

4 MR. LOUIS: Yes, Your Honor.

5 THE COURT: What is it?

6 MR. LOUIS: This morning I've asked Mr. Amann if I
7 could call a witness out of order, Mr. Steven Chao. Mr. Chao
8 purchased some Cialis over the internet and that purchase was
9 referenced in Mr. Xu's computer and it's also an allegation
10 that's part of the indictment as far as Cialis. Mr. Amann
11 thought that it might be 404(b). From my perspective it is
12 part of the indictment.

13 THE COURT: Where is it alleged in the indictment?

14 MR. LOUIS: On Page 4, part of the conspiracy, under
15 C.

16 THE COURT: Okay. I'm looking at Page 4. I don't
17 see anything.

18 MR. LOUIS: If you'll look under the matters to
19 violate the conspiracy -- No. C, to violate the Food, Drug and
20 Cosmetic Act with the intent to defraud and mislead cause a
21 counterfeiting of trademarks Viagra and Cialis in violation
22 of --

23 THE COURT: Do you have any reference to this person
24 in here as a manner or means or overt act?

25 MR. LOUIS: No, I do not because it's part of the

1 conspiracy.

2 THE COURT: Is There any relationship between
3 Mr. Chao and Mr. Xu?

4 MR. LOUIS: Yes, Your Honor.

5 THE COURT: What?

6 MR. LOUIS: The relationship is that Mr. Chao
7 purchased Cialis over the internet. We have receipts of that.
8 And then within Mr. Xu's computer is the actual sale,
9 Mr. Chao's name, his address. So that's the relationship
10 between Mr. Chao and Mr. Xu, the reference of the sale.

11 THE COURT: So Mr. Xu sold the same counterfeit drugs
12 to Mr. Chao?

13 MR. LOUIS: Yes, it's the same milligrams, it's the
14 same as Mr. Xu -- what happened to Mr. Chao, after receiving
15 this information from Mr. Xu's computer; went to Mr. Chao and
16 Mr. Chao provided to the agents the sample that he had of the
17 Cialis that he purchased over the internet. That sample was
18 tested and determined to be counterfeit.

19 THE COURT: So why wouldn't this be admissible?

20 MR. AMANN: Judge, I think it is evidence of a
21 extraneous offense that is outside the scope of this
22 indictment. Number one, I think the evidence will show that
23 they cannot tie the purchase by Mr. Chao from Mr. Xu. I think
24 he purchased from an online pharmacy company and there is no
25 connection between that online pharmacy company and Mr. Xu.

1 THE COURT: Does Mr. Chao have any -- will he testify
2 that he had any personal dealings with Mr. Xu?

3 MR. LOUIS: No, sir, no, Your Honor. He will testify
4 that he made a purchase over the internet after he saw the
5 advertisement. He purchased it over the internet, sent the
6 money to an account and --

7 THE COURT: I think we're going to do this: You can
8 use it, after Mr. Xu testifies, you can use it for purposes,
9 perhaps, of impeachment depending on what he says about the
10 long drug legend that I kept out yesterday.

11 MR. LOUIS: Yes, sir.

12 THE COURT: I'm not going to allow it as part of your
13 case in chief. I think, whether or not it's 404(b) evidence,
14 the potential prejudice far outweighs any relevance. That's
15 my ruling.

16 MR. LOUIS: I understand.

17 MR. AMANN: Judge, I don't want to mislead the Court
18 in any way, implicitly or explicitly, we haven't decided for
19 sure whether, of course, whether Mr. Xu --

20 THE COURT: I understand that. And that's your
21 choice. But I'm just saying if he testifies, it might be
22 relevant then.

23 MR. AMANN: Yes, sir.

24 THE COURT: Okay. Bring the jury in.

25 Did you have any -- by the way, did you have law

1 supporting your proposed language.

2 MR. AMANN: Judge, what I referenced was the
3 indictment itself where the fifth element of my requested
4 charge, which was the one at issue for the Court is actually
5 pled in the indictment as an element so, therefore, I believe
6 it is element of the offense. Since they pled it, they must
7 prove it.

8 THE COURT: He submitted four Fifth Circuit cases,
9 which set out, although there's no argument that the fifth
10 element should be included, they all say, these are the four
11 elements.

12 MR. AMANN: Yes, I've read *Sultan, Hanafy*. I
13 actually pulled those cases when I was putting my requested
14 charge together. But I examined the indictment for the
15 elements that he pled because I don't think there should be
16 any kind of constructive amendment and since the Government
17 has pled that --

18 MR. LOUIS: There's no constructive amendment.
19 That's how you plead the charge. It's been that way --

20 THE COURT: I'll take a look at it.

21 Bring the jury in. We don't want to waste any time.
22 I didn't mean to say "waste." We don't want to delay the
23 trial any longer.

24 (The jury comes in.)

25 THE COURT: Good morning, ladies and gentlemen.

1 Please be seated. Thank you, again, for being here on time.

2 Mr. Sherman, please come around to the witness stand.

3 You may continue your cross-examination.

4 MR. AMANN: Thank you, Your Honor.

5 ROBERT SHERMAN

6 having been previously duly sworn, testified as follows:

7 CROSS-EXAMINATION(con't)

8 BY MR. AMANN:

9 Q. Agent Sherman, good morning.

10 A. Good morning, sir.

11 Q. All right. I want to go back and pick up a little bit
12 where we left off yesterday and I'll try to streamline this --

13 A. Sure.

14 Q. -- and get to the heart of the matter as quick as we
15 possibly can. In the Bangkok meeting, the first meeting that
16 you had with Kevin Xu and, of course, his wife was present,
17 you told us about that, did you ever ask Mr. Xu where his
18 factory, supposed factory was located?

19 A. I don't recall asking him specifically.

20 Q. All right. Did you at any time -- let's not worry about
21 the first meeting -- had you at any time during the
22 conversation with Mr. Xu ask him where his factory was located
23 that manufactured these prescription drugs?

24 A. He told me he had a factory. I can't recall if he
25 specifically said it was in China.

1 Q. All right. But you never asked him where it was?

2 A. No.

3 Q. Did you ever ask him how long he had been in business?

4 A. He volunteered he'd been in business six years.

5 Q. Six years?

6 A. Yes.

7 Q. Did you ask him who worked with him?

8 A. Excuse me?

9 Q. Did you ask who worked with him, if he had any partners,
10 any owners, any --

11 A. Yes, I did.

12 Q. Did he mention anybody?

13 A. He mentioned -- he said he had a partner with an
14 individual in Europe, I believe, operating out of Luxemburg.
15 And then he said that he wasn't directly a partner but a major
16 client for his European distribution.

17 Q. Okay. With respect to the factory and I'm concentrating
18 now on the factory that you claim Mr. Xu supposedly had in
19 China. Did he ever or did you ever ask him whether he had
20 partners or co-owners in that factory?

21 A. I didn't.

22 Q. Did you ever ask him how big the factory was?

23 A. No, I did not.

24 Q. Did you ever ask him how many employees --

25 A. No, I did not.

1 Q. -- were employed at that factory?

2 Now, at some point -- let me -- if I can retrieve
3 these boxes for you. If you can get out your log sheet
4 because I'm going to ask you some dates.

5 A. Okay.

6 Q. Your Honor, may I use the easel right here?

7 THE COURT: Sure.

8 MR. AMANN: Now, let me turn this a little bit so you
9 can see it as well.

10 BY MR. AMANN:

11 Q. Now, this first shipment of drugs came in to you before
12 the Bangkok meeting?

13 A. That's correct.

14 Q. All right. Do you have -- and I'm just going to put
15 No. 1 for that first shipment -- do you have the date for me,
16 sir, when these were received?

17 A. I believe the date was December 13th, 2006, but to
18 confirm it, I would have to look at the exhibit with the
19 correspondence custody receipt.

20 Q. Can I get that for you?

21 A. Yes.

22 Q. Do you know which document it was?

23 A. No.

24 MR. LOUIS: It should be 3-A.

25

1 BY MR. AMANN:

2 Q. That's correct, December 13th, 2007.

3 A. No, '06.

4 Q. '06, I'm sorry. Okay. December 13th, 2006.

5 Now, at some point you got a second shipment, a
6 sample test run; is that right?

7 A. That's correct.

8 Q. I'm not going to -- let me get these boxes out of your
9 way.

10 A. Okay.

11 Q. I don't need to haul all of those --

12 A. Thank you.

13 Q. I don't need to haul them over, I think we can do that
14 without taking out that stuff.

15 Do you know, sir, when that second shipment was
16 received by y'all?

17 A. On or about December 26, 2006.

18 Q. Apparently shortly after the first one.

19 A. That's correct.

20 Q. All right. Now, we have another shipment; is that
21 correct?

22 A. Yes, sir.

23 Q. We'll call that No. 3.

24 A. Yes, sir.

25 Q. When is that shipment?

1 A. February 20th, 2007.

2 Q. All right. Now, do we have another one?

3 A. Before the meeting I believe that's the last one.

4 Q. That's the last one. Now, are there any subsequent
5 shipments? I mean, Is There -- I'm trying to get them all
6 down there.

7 A. Yes.

8 Q. Okay. We have a fourth one?

9 A. On or about -- give me a moment here -- April 10th, I
10 believe, I'll have to look at the exhibit for the next -- the
11 actual exhibit where the chain of custody for the next
12 shipments.

13 MR. LOUIS: 7-A.

14 MR. AMANN: Thank you.

15 THE WITNESS: 7-A is February 20th so it should be
16 the next one.

17 MR. LOUIS: Oh, I'm sorry.

18 MR. AMANN: We've got February 20th.

19 MS. KETTERMAN: 22-A.

20 MR. AMANN: 22-A?

21 MR. LOUIS: 22-A.

22 MR. AMANN: Thank you.

23 A. April 13th, 2007.

24 BY MR. AMANN:

25 Q. April 13th, 2007. Is that it?

1 A. No.

2 Q. One more?

3 A. I think two more.

4 Q. Two more, okay.

5 A. Yes, two more, I believe.

6 MR. LOUIS: 24-A.

7 MR. AMANN: 24-A, thank you.

8 MR. LOUIS: And 26-A.

9 MR. AMANN: Thank you.

10 A. I think there's more than that actually. Okay. Another
11 one on April 13th, 2007.

12 BY MR. AMANN:

13 Q. Two on April 13th, 2007?

14 A. Yes.

15 Q. All right. I'm just going to write in parenthesis out
16 here to the side times two.

17 A. Okay. Is There three? Hold on.

18 Q. All right.

19 A. Let me just make sure. One, two, three.

20 Q. All right. Three.

21 A. And I'd like to see the exhibit for the April 22nd, I
22 believe it should be, 2007.

23 Q. Do you have that exhibit in front of you?

24 A. The receipt, no, I don't, but just to verify for
25 accuracy.

1 Q. Okay.

2 MR. LOUIS: 29-A.

3 MR. AMANN: Thank you.

4 A. Thank you. April 22nd, 2007.

5 BY MR. AMANN:

6 Q. Okay. So April 22nd, 2007. Okay.

7 A. And the final one should be June 12 -- and if I may see
8 the exhibit for that -- 2007.

9 MS. KETTERMAN: That's 38..

10 BY MR. AMANN:

11 Q. Okay. Last one.

12 A. That's correct, June 12th, 2007.

13 Q. June 12th, 2007. So now we have those six shipments that
14 come into you. Are those all of them?

15 A. I think it's eight shipments, isn't it, or nine? I
16 believe it's eight shipments, sir, not six.

17 Q. Sir?

18 A. I believe it's eight shipments, not six.

19 Q. Okay. Are we --

20 A. Let me check here.

21 Q. You've got one that's got three coming in.

22 A. Okay. On dates you're talking about?

23 Q. One, two, three, four, five, six, seven, eight.

24 A. Okay.

25 Q. Are you comfortable that we have them covered?

1 A. Yes.

2 Q. All right. Now, I believe, sir, we talked or the
3 Government talked with you yesterday about a drug alert that
4 came in from somewhere in Europe.

5 A. Yes, sir, MHRA.

6 Q. MHRA, Medical Healthcare Products Regulatory Agency;
7 correct?

8 A. That is correct, sir.

9 Q. And that drug alert, what is the date of that drug alert?

10 A. Dated May 25th, 2007.

11 Q. Okay. So we have the alert May 25th, 2007; right?

12 A. Yes, sir.

13 Q. So I'll let you hang onto those. So it's true, is it
14 not, that these one, two, three, four, five, six, seven of
15 these shipments that came into you from Mr. Xu occurred before
16 the notice of that drug alert on May 25th?

17 A. They were referring to the Plavix drug alert, yes, that's
18 correct.

19 Q. All right. That is correct; right?

20 A. That is correct.

21 Q. Okay. Now, we also talked about whether or not Mr. Xu
22 entered into a contract with you. And I think when you were
23 talking about contracts, you were talking about something that
24 we think of as formalized written piece of paper that
25 memorializes the agreement between the parties; right?

1 A. Yes, sir.

2 Q. Is that fair?

3 A. That's fair.

4 Q. Without me having to relive my law school days, can we
5 agree, sir, just for purposes of our discussion here, that
6 basically a contract involves one side making an offer; right?

7 A. That's half of it, right.

8 Q. That's half of it. I'm not done. The other half or the
9 other third of it is that the other side has to either accept
10 or reject that offer?

11 A. That's correct.

12 Q. Now, and to make things just really square on a business
13 aspect -- from a business aspect we also need what's called
14 consideration. There's got to be money.

15 A. Yes.

16 Q. All right. So you need an offer, the other side has to
17 either accept or reject it, then there's got to be some money;
18 right?

19 A. Most cases, yes.

20 Q. Most cases, yes. Now, did you ever ask Mr. Xu to sign
21 anything for you?

22 A. No. In fact, he specifically said he didn't want a
23 contract, he wanted it oral.

24 Q. He wanted it oral?

25 A. Yes.

1 Q. Are you familiar -- well, Is There a difference between
2 an oral contract and a written contract, so far as you know,
3 what's legally binding?

4 A. I'm not an attorney.

5 MR. LOUIS: I'll object to this witness's competency
6 about legal terms.

7 THE COURT: He already said he's not an attorney.

8 BY MR. AMANN:

9 Q. All right. Now, if we look at Government's Exhibit No --
10 make sure I get the right one here for you -- Exhibit No --

11 MR. AMANN: I'm sorry, Your Honor. If we could turn
12 the Elmo on, please.

13 THE COURT: It should be on.

14 MR. AMANN: It should be on. Then I'm doing
15 something wrong.

16 THE COURT: Have you turned yours on down there?

17 MR. AMANN: It says power.

18 THE COURT: I don't have the projector on. It will
19 take a second.

20 MR. AMANN: Okay. I'm sorry, Judge.

21 BY MR. AMANN:

22 Q. All right. Okay. Government's Exhibit No. 12.

23 A. Yes, sir.

24 MR. AMANN: I'm -- with the permission of the
25 Government, I'm using my copies.

1 BY MR. AMANN:

2 Q. You sent an email to Kevin basically saying please
3 reconfirm your prices for Plavix, Tamiflu and Zyprexa; right?

4 A. That's correct.

5 Q. All right. So you're asking him what does it cost;
6 correct?

7 A. Verify the cost, yes.

8 Q. On Government's Exhibit 13 -- it's already in evidence --
9 you say -- or this is coming from Mr. Xu to you, "Dear Ed,"
10 right?

11 A. That's correct, sir.

12 Q. And he makes you an offer. We can offer you these
13 products for these prices; correct?

14 A. That's correct.

15 Q. So he's made the offer. That's the first part of the
16 contract; right?

17 A. That's the first part of negotiation. I wouldn't
18 characterize it as a contract.

19 Q. Okay. It's the first step toward creating the contract?

20 A. In the event one was finally consummated.

21 Q. Yes. Okay. Let me make sure I don't get them out of
22 order here. You accepted that offer, did you not?

23 A. I did.

24 Q. You did. All right. So he made the offer and you
25 accepted the offer; correct.

1 A. That's correct, sir.

2 Q. And then what Mr. Xu did is he sent you instructions for
3 where you should mail the money?

4 A. Wire transfer the money, yes, sir.

5 Q. Right. So we had him making the offer to you, you
6 accepted the offer and then you paid money?

7 A. That's correct.

8 Q. That's the consideration. So you had a contract with
9 Mr. Xu, didn't you?

10 A. I didn't have a formal contract. I had an agreement,
11 both verbal and email.

12 Q. All right. When you're saying "formal," you're saying it
13 just wasn't written. Is that your definition of being formal?
14 And I don't mean to pick nits with you.

15 A. Yes, I understand. There was no formal written contract,
16 which is usually the case in dealing with such a
17 highly-regulated product as pharmaceuticals. You don't deal
18 in the barter system with pharmaceutical products.

19 Q. Mr. Xu sent you an email, which tells you that the
20 packing or the packaging for these products is designed for
21 the Euro market; right?

22 A. That's correct.

23 Q. What we talked about yesterday, the EU, the European
24 Union; correct?

25 A. That's correct.

1 Q. All right. So obviously from your perspective when
2 you're entering into these negotiations for Mr. Xu, he is
3 telling you, sir, that these products are coming from the
4 European market, isn't he?

5 A. No, he's not telling me that.

6 Q. Well, the packaging is in French.

7 A. It doesn't mean it's coming from the European market.
8 They could be printed in China.

9 Q. If he is telling you that, "What I've got right now or
10 what I can get is French packaging" --

11 A. Yes, sir.

12 Q. -- that indicates to you, does it not, sir, that he is
13 dealing with product that comes from the European market?

14 A. If it was legitimate product, but it's not.

15 Q. Well, I'm not talking about what you know now.

16 A. Okay.

17 Q. All right. I understand that. I'm talking about from
18 the perspective at the time. And at the time he was
19 representing to you what --

20 MR. LOUIS: Objection. Calls for speculation as to
21 what he knew what Mr. Xu knew. That calls for speculation on
22 his part.

23 THE COURT: Let me hear the question again.

24 BY MR. AMANN:

25 Q. At the time, based on this email from reading it, Mr. Xu

1 was telling you that, "What I've got or can get will be in
2 French packaging and, therefore, comes from the European
3 Union"?

4 MR. LOUIS: Objection.

5 THE COURT: Sustained.

6 BY MR. AMANN:

7 Q. The product that you received, was it in French
8 packaging?

9 A. This is the Casodex?

10 Q. Yes.

11 A. Yes, it was.

12 Q. Okay. Now, then Mr. Xu, when you were talking with him
13 both in Bangkok and later at the meeting back here in the
14 United States, he seemed to indicate that he was not concerned
15 with the packaging; correct?

16 A. He was -- well, he would be able to provide or make the
17 packaging if we gave him a sample.

18 Q. So he would be able to provide it for you; right?

19 A. Yes.

20 Q. All right. Now, did you ask Mr. Xu whether he had a
21 factory, separate and apart from making these pharmaceuticals,
22 that he had a factory that was capable of reproducing the
23 printing necessary for the packaging?

24 A. I didn't go that much into detail. But one of the things
25 that Special Agent Mason asked during the meeting in Houston

1 on June 24th, 2007 is whether he obtained the packaging of
2 different products from separate people or from the same
3 individual. He said, no, he got it all together because that
4 was a concern that Special Agent Mason asked that we'd have to
5 get the product from a variety of different sources.

6 Q. Did you ask him whether he owned a factory that
7 manufactured or reproduced the packaging necessary to market
8 the product? That's "yes" or "no," either you did or you
9 didn't.

10 A. I don't recall.

11 Q. All right. Did you ever ask Mr. Xu during any of your
12 negotiations, either in Bangkok or back here in the United
13 States, what was the biggest order he had ever filled?

14 A. Yes, I did.

15 Q. What was the biggest order he had ever filled?

16 A. I don't recall him giving a specific answer on that.

17 Q. All right. So he didn't answer that question?

18 A. I don't recall that he gave a specific answer.

19 Q. With regard to the biggest order that he had ever filled,
20 did he tell you how long it took him to fill that order?

21 A. I'm not sure whether it's in the context of that
22 question. I know that he had made statements that they could
23 do large production runs. He talked about 10,000 tablets. He
24 even talked, I believe, 100,000 production run and it would
25 take two months to prepare for that run.

1 Q. Okay. So he told you that it would take two months to
2 prepare to fill a big order?

3 A. Yes.

4 Q. All right. And at the same time he's saying, "I've got a
5 factory that can do it"?

6 A. Yes.

7 Q. All right. At the time?

8 A. Yes.

9 Q. Okay. Now, I think it was at the second interview, the
10 conversation in the United States, Mr. Xu said he worked for a
11 petrochemical company?

12 A. That was another one of his ventures, yes.

13 Q. All right. Did you ever ask him who that was?

14 A. I asked where it was located and we were able to find it.

15 Q. And where is that?

16 A. I believe it was in Jacksonville, Florida.

17 Q. And you were able to verify that Mr. Xu --

18 A. He had some relationship. We didn't know the extent of
19 the relationship.

20 Q. Did you try to determine the extent of that relationship?

21 A. No, we did not.

22 Q. Did Mr. Xu tell you during his interview that he dealt
23 in -- second interview here in the United States -- he dealt
24 in steel?

25 A. He had a -- several commodities. Steel may have been one

1 of them. I don't recall what they were.

2 Q. Petrochemicals?

3 A. Petrochemicals, solids.

4 Q. Raw materials?

5 A. Yes.

6 Q. All right. So various array of things that he was
7 involved with?

8 A. That's correct.

9 Q. That he was a trader for. Now, the sample order, the --
10 whatever run -- which one of these eight -- we have actually
11 six shipments coming in and several of them were samples just
12 to make sure that it was going to verify your --

13 A. Let me be more specific of what we mean by "samples,"
14 first of all.

15 Q. Okay.

16 A. I think that may be a little confusing.

17 Q. Let me ask you this question then.

18 A. Okay.

19 Q. The sample run was to make sure that what he was able to
20 deliver he could deliver and you guys received it okay?

21 A. They were all characterized as sample runs. And there's
22 a reason for that.

23 Q. All right. Now, after Mr. Xu made these eight some odd
24 deliveries to you, I believe he was told that everything was
25 fine, this was good product; right?

1 A. We were satisfied with the product.

2 Q. And during the second meeting, the meeting in the United
3 States between you and -- was it Doug Mason?

4 A. Special Agent Mason, yes, sir.

5 Q. He was posing as a doctor?

6 A. Yes, that's correct.

7 Q. He was a medical doctor?

8 A. Medical doctor.

9 Q. And during that meeting he, in fact, told Mr. Xu that
10 we've received your, quote, sample runs, end quote, and
11 everything looks great; correct?

12 A. Yes, he did.

13 Q. All right. Mr. Xu was never told -- you never told him
14 there was a problem with anything, did you?

15 A. As far as a problem, no.

16 Q. Okay. Now, Mr. Xu -- or I believe you described, and you
17 can correct me if this was at the Bangkok meeting or at the
18 meeting here in the United States, that Mr. Xu described your
19 relationship or his relationship between you and he as very
20 special?

21 A. Yes, sir, that's correct.

22 Q. All right. And I believe you emphasized that in your
23 testimony that your relationship was -- that he said it was
24 special.

25 A. That's correct.

1 Q. Now, sir, do you think it's unusual for a businessman
2 who's trying to get somebody's business to make them feel like
3 they're a very special customer?

4 A. Happens all the time.

5 Q. What you were trying to do at both the Bangkok meeting
6 and at the meeting in the United States, you were trying to
7 get Mr. Xu's business, weren't you?

8 A. I was trying to ascertain whether Mr. Xu was involved in
9 criminal activity.

10 Q. And you were trying to get his business?

11 A. I was trying to ascertain if he was involved in criminal
12 activity. I'm not a businessman, I'm an undercover agent,
13 sir.

14 Q. But you were posing as a businessman?

15 A. That's correct.

16 Q. And your persona as a businessman, you've got to play
17 your part; right?

18 A. That's correct, yes.

19 Q. And your part was, go out and get this guy's business?

20 A. That's correct.

21 Q. Okay. Now, he wasn't playing a part, was he?

22 A. No, he really was a counterfeiter.

23 Q. Oh, he really was a counterfeiter?

24 A. Yes.

25 Q. That's your conclusion, isn't it?

1 A. Yes.

2 Q. Is it your job as a special agent to decide who is guilty
3 or not guilty or is that these people's job?

4 MR. LOUIS: Objection. Argumentative.

5 THE COURT: Overruled.

6 A. Sir?

7 BY MR. AMANN:

8 Q. Is it your job as a person who is in law enforcement to
9 decide who is guilty or not guilty or is it the province of
10 the jury?

11 A. It's for the jury, sir.

12 Q. So it's not your job to go out and say, "You're guilty,
13 you're guilty, you're guilty," your job is to collect
14 evidence --

15 A. That's true, sir.

16 Q. -- and let these people decide.

17 A. That is true, sir.

18 Q. All right. Mr. Xu in your persona -- your persona was,
19 "I'm in business. I want to get his business." And Mr. Xu
20 was trying to get your business, wasn't he?

21 A. That's correct.

22 Q. All right. Now, we heard a recorded telephone
23 conversation where you tried to call Mr. Xu.

24 A. That's correct.

25 Q. And apparently you got his home number.

1 A. I think it was an office, I'm not certain.

2 Q. You're not certain whether it was his home or office
3 number?

4 A. That's correct.

5 Q. And you were given his cellphone number?

6 A. I believe his cellphone, yes.

7 Q. Were you ever able to discover who his cellphone provider
8 was?

9 A. No, I wasn't.

10 Q. Did you ever try to find that out?

11 A. It was in China and we don't have access to those
12 records.

13 Q. Are you saying that AT&T, Sprint and all those people
14 that provides cellphone service don't have international
15 service as well?

16 A. I'm not aware that was his provider.

17 Q. During the meeting that you had with Mr. Xu here in the
18 United States we can hear a cellphone ring and he actually
19 answers the phone, doesn't he?

20 A. That's correct.

21 Q. So the cellphone he was using was working in the United
22 States, wasn't it?

23 A. Yes, but your provider can be anywhere in the world.

24 Q. All right. Did you try to find out who his provider was
25 so you could track down his cellphone records to see who he

1 was calling and who was calling him?

2 A. No, we did not.

3 Q. You also had his bank account information, didn't you?

4 A. I don't recall what bank account information we had of
5 his.

6 Q. Well --

7 A. I'd have to see the exhibit. When you say "bank
8 account," are you talking about transaction activity or just
9 the name of the account?

10 Q. The name of the account that you were actually wiring --
11 here they are. We've got Government's Exhibit No. 17 that's
12 kind of hard to read. But you had bank account information,
13 the Beijing bank account, there's an address, there's a block
14 located in Beijing; right?

15 A. That's correct.

16 Q. So you knew where your money was going?

17 A. That's correct.

18 Q. This is the money that you as a businessman were paying
19 Mr. Xu for his product; right?

20 A. That's correct.

21 Q. You knew where this money was going. We also have in
22 Government' Exhibit 20 he provided you the name of the
23 business --

24 A. That's correct.

25 Q. -- with an account number, again, an address, where to

1 send your money; correct?

2 A. That's correct, sir.

3 Q. All right. Now, when you first met him, I think you
4 testified yesterday, you never got a card from him.

5 A. I did get a card, but I lost it.

6 Q. But you lost it. He represented himself to be working
7 for Orient Pacific International, Limited; right?

8 A. That's correct.

9 Q. And at all times during your dealings with Mr. Xu that's
10 who he represented was his business; correct?

11 A. Yes.

12 Q. I believe yesterday we were talking about the very first
13 sample that was sent to you December 13th, 2006.

14 A. Yes, sir.

15 Q. I believe the Court asked you whether you still had the
16 box that that stuff had been shipped in and you said you had
17 destroyed that box.

18 A. Yes, sir.

19 Q. Now, we have, after the first one, we have one, two,
20 three, four, five, six, seven other shipments; right?

21 A. Yes.

22 Q. Do you have those boxes?

23 A. No, not to my knowledge. I don't think I do.

24 Q. Did you destroy all those boxes?

25 A. I believe so, yes.

1 Q. Now, let me try to move this out so we can see.

2 Okay. Sandra was an undercover operative for Eli
3 Lilly who is the big drug manufacturer; right?

4 A. That's correct, sir.

5 Q. We talked a little bit about her yesterday. I don't need
6 to go over that. In this email, which is Government's Exhibit
7 No. 20, Kevin is telling you: Okay. I'm sending you these
8 samples and here are the tracking numbers; correct?

9 And, by the way, when you wire money to a bank, there
10 is a paper trail created, isn't there?

11 A. Yes, sir.

12 Q. When you send something either by Federal Express, EMS,
13 however, we have to fill out a receipt, a paper trail is
14 created?

15 A. Yes, sir.

16 Q. So it's easy to trace where stuff went and where it came
17 from; correct?

18 A. Yes, sir.

19 Q. All right. Now, Sandra in this email which, again, is
20 Government's Exhibit No. 20, this is Kevin talking to you;
21 right?

22 A. Yes, sir.

23 Q. It says, "Also Sandra asked us to send one his parcel to
24 your address also, please pay attention on it, the Sandra's
25 mail no. is" -- now, did Sandra send you guys something?

1 A. No.

2 Q. So --

3 THE COURT: Did Sandra order the first two shipments?
4 I'm not clear on that.

5 THE WITNESS: Well, Sandra on behalf of Eli Lilly
6 ordered the first, I believe it was, three shipments but they
7 were sent piecemeal. So I think there was a total of four or
8 five of them were on behalf of Eli Lilly.

9 THE COURT: How did you get involved? Did Sandra
10 introduce you through the internet first?

11 THE WITNESS: I beg your pardon, sir, could you
12 repeat that?

13 THE COURT: How did you first come in contact with
14 Mr. Xu before you physically met him in Bangkok?

15 THE WITNESS: That was the purpose of the meeting
16 to -- in Bangkok. She was going to introduce me at that point
17 and that's when we were introduced.

18 THE COURT: There was no email contact with him
19 before that?

20 THE WITNESS: I don't recall. I think we did, sir.

21 THE COURT: But you had received the package from him
22 before then.

23 THE WITNESS: Yes, she provided the address.

24 THE COURT: And he sent them to you at her request?

25 THE WITNESS: That's correct.

1 THE COURT: All right. Thank you.

2 BY MR. AMANN:

3 Q. Okay. I think that clears it up. Also, Sandra asked you
4 to send -- we're talking about just what the judge was asking
5 you about. They were kind of working together on this; right?

6 A. It was an order that Sandra made. And it was sent to our
7 box so we could assume possession of it as evidence and have
8 it analyzed.

9 Q. And that's what Sandra's talking about, that's what Ed --

10 A. I'm Ed, sir.

11 Q. That's what Kevin is talking about here in his email to
12 persona Ed?

13 A. That's correct, sir.

14 Q. All right. I got it. Thank you very much.

15 Did -- let me see if I can find this exhibit,
16 Government's Exhibit No. 57. Let me grab it out of here for
17 you so that you'll have a copy of it in front of you. That
18 way you don't have to --

19 A. Yes, sir.

20 Q. All right. Government's Exhibit No. 57. And I'm going
21 to have to shrink it a little bit. That's the wrong way
22 again. Hopefully everybody is seeable.

23 Okay. I believe you testified yesterday, sir, that
24 you compared the prices that Kevin was charging you with the
25 retail prices of these same prescriptions; correct?

1 A. Yes, sir.

2 Q. Now, retail is what a pharmacy sells to us for at a
3 price?

4 A. A consumer walking in buying the drug.

5 Q. Right, that's retail.

6 A. Yes, sir.

7 Q. Now, did you ever ask the pharmacies what they pay for
8 the product from the wholesaler-manufacturer?

9 A. I don't recall. I don't think I did.

10 Q. Could we agree, sir, that the retail value of these
11 prescription drugs is going to be greater than what the
12 wholesale value is?

13 A. That's correct, sir.

14 Q. Because the pharmacy companies are certainly in business
15 to make money, like any business; right?

16 A. Yes, sir.

17 Q. And the only way they make money is to sell it to
18 pharmacies at such a profit that they themselves can make
19 money and then the pharmacies inflate that price and sell it
20 to the consumer; right?

21 A. They sell it at a premium to make a profit.

22 Q. Right. You said it a lot better than I did. So in this
23 scenario we have manufacturer, we have pharmacies and then at
24 the very end we have consumer; right?

25 A. Yes, sir.

1 Q. That's the chain of economic flow, if you want to call it
2 that.

3 A. Pretty simplistic characterization, but that's pretty
4 good.

5 Q. I'm a simplistic guy. What happens is, the price -- the
6 pharmacies are actually -- they're middlemen, the pharmacies
7 are the middlemen, the ones who deal with --

8 A. I don't know if you would characterize them as a
9 middleman or the final dispenser.

10 Q. Well, in my simplistic hypothetical we have manufacturer,
11 pharmacies and consumer; the pharmacy is the middleman; right?

12 A. Well, without --

13 THE COURT: Let's move along. We all got the drift
14 here.

15 MR. AMANN: I'm sorry, Judge.

16 BY MR. AMANN:

17 Q. You did not determine what the wholesale value was, did
18 you?

19 A. No, I did not.

20 Q. Did you ever call any insurance companies to see what
21 they -- what kind of payment they allow --

22 A. No, sir, I did not.

23 Q. -- for these drugs?

24 A. No, sir.

25 Q. So you don't know what the manufacturer charges for these

1 drugs, do you.

2 A. No, I don't.

3 Q. We can agree, though, it's going to be less than the
4 retail value that we see here on Government's Exhibit No. 57?

5 A. Yes, sir, it would be.

6 Q. But we don't know how much less?

7 A. No, we don't.

8 Q. Could be a lot?

9 A. Could be.

10 Q. And if it's a lot less, if the wholesale price is a lot
11 less, then there's not that -- there could not be that much
12 difference between what Mr. Xu was selling it for and what you
13 were paying for; right?

14 A. I don't know that.

15 Q. You don't know because you didn't check. When Mr. Xu
16 came to the United States to meet with you and Dr. Doug, he
17 brought his wife with him?

18 A. That's correct.

19 Q. He came for the purpose of meeting you and Dr. Doug to
20 see if he could do business with you -- more business with
21 you?

22 A. That's correct.

23 Q. His -- at all times was Mr. Xu concerned that the -- and
24 this is on the tape recording, I suppose the jury can listen
25 to this for themselves? His biggest concern was the packaging

1 and by that I mean, "You want U.S. packaging, I've got Euro
2 packaging." That was a big concern for everybody, wasn't it?

3 A. Certainly that was a significant issue, the packaging.
4 There were other issues also.

5 Q. But he said he could do the packaging?

6 A. He said if we provide a sample, yes.

7 Q. All right. And you have -- well, I think I've already
8 asked that question. During your conversation with Mr. Xu he
9 referred to an HPLC machine?

10 A. Yes.

11 Q. Some kind of analytical device?

12 A. Some very sophisticated, I guess, chemistry test
13 instrument.

14 Q. All right. He didn't seem to know much about it, did he?

15 A. I didn't know much about it so I didn't know what to ask
16 him.

17 Q. Okay. And you have no idea how much one of those
18 machines cost?

19 A. No, I don't.

20 Q. Okay. During your meeting with Mr. Xu, the meeting in
21 the United States, many times during that meeting Mr. Xu talks
22 about parallel importers, doesn't he?

23 A. I don't recall it being many times, I can only recall it
24 being one or two. He did mention parallel importers.

25 Q. And he was trying to -- you didn't understand it at

1 first. He had to say it a couple of times for you to
2 understand --

3 A. I believe so, yes - --

4 Q. -- parallel. He was saying it but his first language is
5 Chinese.

6 A. Yes, sir.

7 Q. During that meeting was there anybody there that could
8 have been available to translate in Chinese for him?

9 A. No.

10 Q. So that -- okay. During or at the end of the meeting,
11 obviously Mr. Xu was arrested. And did he have his computer
12 with him?

13 A. Yes, he did. He had a laptop with him when he came to
14 the meeting.

15 Q. Okay. Was the laptop out in his car, was the laptop
16 actually -- did he walk into the meeting with it?

17 A. He carried it into the meeting with him.

18 Q. He carried it into the meeting?

19 A. Yes, sir.

20 Q. Okay. So I guess he must have sat it down because the
21 first seven minutes or so on the tape it's messed up, we don't
22 see what's going on; right?

23 A. I don't recall what he did with it.

24 Q. All right. You took his computer; right?

25 A. That's correct.

1 Q. He signed a consent to search the computer, didn't he?

2 A. Yes, he did.

3 Q. He said, "Y'all can got into my computer and find
4 whatever you need to find"; right?

5 A. Yes.

6 Q. He allowed you to do that?

7 A. He signed a consent, yes, sir.

8 Q. But beyond that, he also provided you password so that
9 you could access accounts, didn't he?

10 A. Yes, he did.

11 Q. Okay. So he gave you his computer and he also gave you
12 passwords to get into his various and sundry accounts?

13 A. Yes, sir.

14 Q. So you would have access to everything?

15 A. Yes, sir.

16 Q. So it's fair to say he cooperated in that regard?

17 A. In that regard he did, yes.

18 Q. Now, do you know anybody named Terence Blackett?

19 A. Yes, there are emails from Mr. Blackett --

20 Q. Okay.

21 A. -- in the computer.

22 Q. By "emails" you're talking about emails on his computer?

23 A. Yes, I believe there's some correspondence. I'd have to
24 review it again.

25 Q. I'm going to show you what's marked as Defendant's

1 Exhibit 1, 2, 3. And the last exhibit, 3, actually contains,
2 including the pages itself, four pages -- I take that back,
3 five pages. And they are in reverse chronological order. So
4 I'm probably going to be talking about them with Defendant's
5 Exhibit 4 first. I just want you to look at them; okay?

6 A. Yes.

7 Q. Okay. Through with them all? Okay. Thank you.

8 Now, these defense exhibits that I've shown you, they
9 are from a Terence Blackett and they're actually to Kevin Xu
10 at the same email number that you used when you were
11 corresponding to and from Mr. Xu; correct?

12 A. That's correct.

13 Q. These come from Mr. Xu's computer?

14 A. That's correct.

15 Q. He consented for you to look in that computer and
16 actually gave you password to access it?

17 A. Could you repeat that?

18 Q. Yes, he allowed you to access his computer and gave you
19 password for his account?

20 A. That's correct.

21 MR. AMANN: All right. Your Honor, I'm going to -- I
22 can do it one at a time or I can do it all together but I'm
23 going to offer Defendant's Exhibit 1 through 4.

24 MR. LOUIS: Objection. Lack of foundation in this
25 witness, hearsay as well.

1 THE COURT: Seems to me they're clearly hearsay.

2 MR. AMANN: Judge, if -- first of all, I'm not
3 offering them for the truth.

4 THE COURT: What are you offering them for?

5 MR. AMANN: I'm offering them to show what impact
6 they had on Mr. Xu's state of mind.

7 THE COURT: He had no knowledge of Mr. Xu's state of
8 mind.

9 MR. AMANN: But these emails create an inference of
10 what Mr. Xu was thinking at the time relevant to --

11 THE COURT: I disagree. That's clearly a hearsay
12 purpose. The objection is sustained unless you can lay a
13 proper predicate.

14 MR. AMANN: And certainly not to quarrel with the
15 Court, but the Court understands that I'm not offering them
16 for the truth.

17 THE COURT: You say that, but the stated purpose
18 really is to show how Mr. Xu perceived them.

19 MR. AMANN: Right.

20 THE COURT: If that's the purpose, then these
21 documents would not show that, only Mr. Xu would be able to
22 show that. For the same reason I've not allowed other people
23 to speculate about Mr. Xu's state of mind, it would be
24 improper to allow a document to testify about his state of
25 mind.

1 MR. AMANN: May I make another argument as well?

2 THE COURT: Sure.

3 MR. AMANN: May I approach, Your Honor?

4 THE COURT: Yes.

5 (A bench conference was held outside the presence of
6 the jury.)

7 MR. AMANN: Judge, I'm not offering them for the
8 truth. But the affect of -- what the Government is alleging
9 is that Mr. Xu had the specific knowledge that the product he
10 is dealing in was counterfeit. These emails show that Mr. Xu,
11 whether they're true or not, from Mr. Xu's perspective had a
12 reasonable expectation that he may have been dealing directly
13 with somebody who was dealing with the manufacturer and,
14 therefore, the product would not have been counterfeit. And
15 it strikes at the very heart of his intent. If they're not
16 offered for the truth, they certainly can be offered to show
17 Mr. -- how it would have affected Mr. Xu in his actions and it
18 rebuts the inference that the Government's trying to create
19 that he knew all of that.

20 THE COURT: What's your response?

21 MR. LOUIS: How can he do that when he knows the very
22 nature of his state of mind and what he knew. I mean, it's
23 clear --

24 THE COURT: I'll tell you what, the trial's not going
25 to be over in the next hour. You find some law to support it

1 and I'll consider it. Right now my objection, you got plenty
2 of time, you've got two people sitting at your table, if you
3 can find some law -- I understand your purpose.

4 MR. AMANN: Judge I'm finished with this witness.
5 Will I be permitted to --

6 THE COURT: You can call him back if you can find
7 some law to support it. I've read the documents. I
8 understand.

9 MR. AMANN: Okay.

10 THE COURT: But I just want some law that you can
11 prove through this witness.

12 MR. LOUIS: From introducing emails or --

13 THE COURT: Have a seat.

14 (Bench conference concluded.)

15 THE COURT: Ladies and gentlemen, there's nothing
16 wrong with the lawyers wanting to approach the bench.
17 Sometimes -- how many football fans do we have? Sometimes in
18 a football game the referees will throw down those flags and
19 people get penalized. I've made some rulings dealing with
20 evidentiary issues and the lawyers know that rather than
21 running a risk of me throwing down the yellow flag in the
22 middle of a trial, the safest thing is to come to the bench
23 and find out how I'm going to rule in advance. So we don't do
24 it very often, but in certain situations they want to come to
25 the bench and get a ruling. It's perfectly appropriate.

1 Go ahead.

2 MR. AMANN: Thank you, Your Honor. May I have just a
3 moment?

4 THE COURT: Yes, of course.

5 BY MR. AMANN:

6 Q. Mr. Sherman, you created a report throughout the course
7 of your investigation?

8 A. Yes, sir.

9 Q. Do you have that report with you?

10 A. There's a binder of reports, yes, sir.

11 Q. I just noticed you had something in your pocket. Is that
12 a copy of this or --

13 A. No, it's not, it's my work product.

14 Q. I'm sorry?

15 A. It's a timeline.

16 Q. It's your timeline?

17 A. Yes.

18 Q. And do you use that to help you refresh your
19 recollection?

20 A. Because there's so many chain of custody numbers and
21 dates so I can put them together.

22 Q. All right. May I see that, please, sir? And, sir, while
23 I'm looking at this, if you could just browse through these
24 documents, I just want to make sure we got everybody's report
25 covered.

1 A. I don't know what specific report -- there's a lot of
2 reports here. I don't know what -- Is There a specific report
3 you want to look at?

4 Q. No. I just want to make sure that the reports that you
5 created, the ones that you were responsible for creating --

6 A. I believe they're all here.

7 Q. They're all here. Did you create any other tape
8 recordings or videotapes other than the ones that we've
9 already seen here in Court and heard here in Court?

10 A. No, I don't believe I did.

11 Q. Thank you. Do you know, Mr. Sherman, if Mr. Xu ever
12 ordered any prescription medication from Eli Lilly?

13 A. Not that I'm aware of.

14 Q. Do you know if Mr. Xu ever dealt directly with any
15 manufacturers when placing his orders that were eventually
16 destined for you?

17 A. I have no knowledge of that.

18 Q. Would that be something that would be important for you
19 in terms of the investigation you did?

20 A. Well, let me be more specific in my answer. I apologize.
21 Inquiries made with the security division said that he was
22 never a client or -- of the respective companies that are
23 involved in this case.

24 Q. Okay. So the inquiries that you made said that he was
25 never a client or never involved with any of the manufacturers

1 in this case; right?

2 A. Said he was not -- he was not -- did not have a
3 commercial relationship with them.

4 Q. So you're saying he did not have any kind of commercial
5 relationship with anybody from Eli Lilly?

6 A. That's a different question.

7 Q. Is Eli Lilly the drug manufacturer -- is Eli Lilly a drug
8 manufacturer --

9 A. It is a drug manufacturer, yes.

10 Q. -- of some of the drugs that we're talking about here
11 today? And we have to try not to talk over each other because
12 of --

13 A. I'm sorry.

14 Q. -- this lady right here -- thank you. And I'll try.

15 Is Eli Lilly one of the drug manufactures that
16 manufactured some of the drugs that we're talking about here
17 over the past couple of days?

18 A. Yes, sir.

19 Q. And you testified that you checked with Eli Lilly and
20 they told you that Mr. Xu had no kind of commercial
21 relationship with them; is that what you're saying?

22 A. That's correct.

23 Q. May I approach, Your Honor?

24 THE COURT: Sure.

25 (There was a bench conference held outside the

1 presence of the jury.)

2 MR. AMANN: Judge, for purposes of impeachment he had
3 said he checked with Eli Lilly and that Mr. Xu had no personal
4 relationship with him. For purposes of impeachment and not
5 offered for the truth of the matter asserted, I would renew my
6 request to the Court.

7 THE COURT: Go ahead.

8 MR. LOUIS: The indictments don't show Mr. Xu ever
9 had any relationship. The indictments don't say that.

10 THE COURT: You need to show that Mr. Sherman was
11 aware of this document. They're not relevant to impeach
12 Mr. Sherman.

13 MR. AMANN: I apologize for approaching, Your Honor.

14 THE COURT: That's okay.

15 (Bench conference concluded.)

16 MR. AMANN: I will pass the witness Your Honor.

17 THE COURT: Okay. Mr. Lewis, do you have any
18 redirect of Mr. Sherman?

19 MR. LOUIS: Just a little Your Honor.

20 REDIRECT EXAMINATION

21 BY MR. LOUIS:

22 Q. Agent Sherman, Mr. Amann asked you about reviewing or
23 obtaining bank information, cell phone information. Do you
24 remember those questions?

25 A. Yes, I do, sir.

1 Q. Is that information relevant if you're trying to
2 determine who it is that you're dealing with?

3 A. Perhaps the identity but if I know who they are already,
4 I don't need that.

5 Q. And did you -- by meeting Mr. Xu in March 6 of '07, what
6 was the purpose of that meeting?

7 A. The purpose of that meeting was to put a face to the
8 individual, to negotiate directly with him rather than any
9 type of industry, intermediary and affect purchases and
10 ascertain whether those are counterfeit drugs and ascertain
11 his true identity.

12 Q. At the conclusion of that meeting, were you discussing a
13 legal business venture or illegal business venture?

14 A. It was an illegal business venture.

15 Q. And what was said during that meeting that led you to
16 conclude that this was an illegal business venture?

17 A. A variety of things, but one, the issue of no written
18 contract.

19 Q. Anything else?

20 A. The fact of the packaging, the issues discussing the
21 packaging, the ability to produce packaging or provide
22 packaging from different markets, which is highly unusual.
23 And, also, there was an extraordinary breadth of products
24 available, every kind of product across the spectrum. That's
25 highly unusual for an individual to provide that much.

1 BY MR. LOUIS:

2 Q. Do you recall if Mr. Xu mentioned, "I don't know," "you
3 don't know," "we don't know"?

4 A. In the context of the meeting, which was memorialized on
5 the tape in the Bangkok meeting, he provided a very, very
6 detailed scenario for entering these pharmaceutical products
7 into the United States. Pharmaceutical products are not
8 included -- legitimate pharmaceutical products are not
9 included concealed under a fresh protect pack under chemicals
10 mis-described in violation of the law as another item. They
11 were being smuggled into the United States. That is not
12 consistent with the legitimate and legal importation of
13 pharmaceutical products.

14 Q. At the meeting, the July 24th meeting, you made certain
15 statements to Mr. Xu about you have the -- making it and
16 selling it.

17 A. Yes.

18 Q. When you were talking about making it, what were you
19 referring to?

20 A. I was talking about Mr. Xu's role in this transaction.

21 Q. Did Mr. Xu at any point in time indicate he had to get
22 the drugs from another source?

23 A. No. In fact, he responded to the contrary.

24 Q. You mentioned sample run. Can you explain to us what you
25 meant by the "sample run"?

1 A. Okay. The term "sample" may be a little confusing.
2 Usually when an individual buys pharmaceutical products and
3 they ask for samples -- first of all, when you do legitimate
4 products, you don't ask for samples. If it's a legitimate
5 product and you want legitimate Lipitor, you order the
6 Lipitor, you don't order samples because you don't have to
7 examine it and make sure the box is right, make sure the
8 tablets are the right color, to make sure the blister pack is
9 perfect and it has the right color and shading. You don't do
10 that because it's legitimate product. In this particular case
11 we ordered samples to make sure that the quality was
12 consistent, which is highly unusual, and that he would be able
13 to provide it. And when I say "samples" in this specific
14 scenario, usually when an individual orders samples of any
15 product, any commodity, they order a small amount. This was a
16 very large amount for samples. This is not a large amount
17 because Mr. Xu conveyed to me that he could do 5,000 to
18 10,000 boxes per order. We wanted to express interest in
19 doing that, but we work for the United States Government and
20 we can't spend taxpayers' money on buying a couple of hundred
21 thousand dollars worth of product so we represented these as
22 large samples to provide to our client.

23 Q. Now, during the meeting, the July 24th meeting, do you
24 recall if Mr. Xu mentioned he had what's called a HPLC test?

25 A. Yes, he had access to HPLC and they did testing.

1 Q. And why was Mr. Xu telling you he had access to an
2 HPLC --

3 MR. AMANN: Speculation. I object, Your Honor.

4 THE COURT: Sustained.

5 BY MR. LOUIS:

6 Q. Did Mr. Xu indicate where he obtained that HPLC machine?

7 A. I believe from Germany.

8 MR. LOUIS: I pass the witness.

9 THE COURT: Mr. Amann, anything else?

10 MR. AMANN: May I, Your Honor?

11 RECROSS-EXAMINATION

12 BY MR. AMANN:

13 Q. Is Mr. Xu charged with illegally smuggling prescriptions
14 into the United States?

15 A. I'd have to look at the indictment again, the initial
16 charges. I'm not sure there's a 545 charge on there.

17 Q. Well, if I tell you he's not, would that surprise you?

18 A. That would surprise me.

19 Q. All right. Is it against the law to bring real
20 pharmaceuticals into the United States from another country?

21 A. No, it's not.

22 Q. It's not illegal to ship Eli Lilly's product from France
23 into the United States without Eli Lilly being aware of it?

24 A. That, I don't know.

25 Q. If Eli Lilly and other drug manufacturers that we're

1 talking about, is it fair to say, sir, that they want to
2 market their product here in the United States at the price
3 they deem appropriate for the United States?

4 A. Yes, I guess you can say that.

5 Q. Is it also fair to say that if -- if other legitimate Eli
6 Lilly product comes into the United States, it is going to
7 dilute the amount of money that Eli Lillie will make, won't
8 it?

9 A. If it's legitimate product, it could, yes.

10 Q. So if you have -- I'm going to define the word
11 "legitimate product" as real prescriptions manufactured by Eli
12 Lillie in the United States. That's my definition of
13 legitimate product. Okay?

14 A. May or may not be correct because I don't know where they
15 manufacture.

16 Q. This is my hypothetical.

17 A. Okay. I'll give you a hypothetical answer then.

18 Q. Okay. That's fine. That would be lovely.

19 You've got legitimate Eli Lilly product in the United
20 States. If Eli Lilly product comes into the United States
21 that is real, that is genuine, but it's imported from another
22 country at a lesser price, it takes away from the profit that
23 Eli Lilly makes, doesn't it.

24 A. Depends to which network it's distributed and sold
25 through. And that's an economic and marketing issue that I'm

1 not qualified to answer.

2 Q. Okay. You certainly see how it could though?

3 A. I'm not qualified to answer that question.

4 Q. All right. If legitimate product existing in the United
5 States is mixed with genuine product, genuine prescriptions
6 that come in from Europe, the product itself is not thereby
7 rendered counterfeit; is it?

8 MR. LOUIS: Objection. Calls for legal conclusion on
9 behalf of this witness. He's not competent to answer that
10 question.

11 THE COURT: I'm going to sustain it because it's
12 beyond the scope of redirect. We're really getting --

13 MR. AMANN: Okay.

14 THE COURT: It's the tautological question. The
15 argument is, if you import drugs, it's not illegal. Well,
16 that's obvious. So let's move on to something else.

17 MR. AMANN: Okay.

18 BY MR. AMANN:

19 Q. We talked about it on redirect, the Government asked you
20 about bank information and cellphone information as part of
21 your investigation. It's important to you, sir, isn't it, to
22 not just investigate instances of misconduct but also to
23 verify if conduct is legal?

24 A. That's correct.

25 Q. Because it's not your job to convict, it's your job to

1 conduct an investigation and be fair, isn't it?

2 A. Yes, sir.

3 Q. All right. So in being fair, you want to pursue every
4 possible investigative trail you can to make sure that the
5 person you're charging is the right person to be charged;
6 right?

7 A. Yes, sir.

8 Q. All right. Mr. Lewis talked about the absence of a
9 written contract again.

10 A. Yes, sir.

11 Q. We went over all of that. I just want to ask this
12 question again to make sure it's clear: You never put a piece
13 of paper in front of Mr. Xu and said, "here's our deal, I want
14 you to sign it," did you?

15 A. No, he told me not to.

16 Q. He asked you not to?

17 A. He said he wanted an oral contract so that would be
18 tantamount to telling me he didn't want a written contract,
19 sir.

20 Q. And you were going to do what he wanted; right?

21 A. If he was involved in an illegal enterprise, I was going
22 to follow his lead, yes, sir.

23 Q. As far as the packaging goes -- and there's been a lot
24 said about the packaging. And let me try to give a visual
25 example to you. Government's Exhibit 21.

1 A. Could I look at that for a moment, please?

2 Q. Oh, sure.

3 A. This is in the wrong box. This has nothing to do with
4 this exhibit.

5 Q. I tell you what, it's Government's Exhibit 6 and it will
6 serve for purposes of my illustration. As we've talked about
7 packaging and how important packaging is; right?

8 A. Yes, sir.

9 Q. And you claim that there's some evidence that Mr. Xu knew
10 the stuff was counterfeit simply because -- and let's use this
11 as an example -- sometimes it came in just pills --

12 A. Yes.

13 Q. -- and sometimes it came together with the packaging
14 without the pills being in the packaging?

15 A. That's correct.

16 Q. All right. Now, if you're dealing in the European
17 market, for example -- I'm pulling something right now for the
18 record out of Government's Exhibit No. 6, which is a box of
19 Plavix that clearly the packaging is in French, isn't it?

20 A. That's correct, sir.

21 Q. Now, he couldn't -- he sent this to you?

22 A. Yes, he did.

23 Q. All right. So he sent you packaging that was in French?

24 A. That's correct, sir.

25 Q. That demonstrated to you, did it not, sir, that this

1 stuff was coming from a European market?

2 A. No, it did not.

3 Q. There's certainly some indication, isn't it?

4 A. The -- the language on the box is irrelevant to the
5 source of production. Any language could be put on that box.

6 Q. Any language could be put on that box. Are you telling
7 me, sir, that the language, since it is in French in this case
8 is no indication whatsoever that this stuff came from France?

9 A. I see -- it's interesting you selected that particular
10 box.

11 Q. My question is --

12 A. Okay.

13 Q. -- is that is the fact that it's in French from your
14 perspective --

15 A. From my perspective.

16 Q. -- that's no -- and this is a statement I'm trying to get
17 you to agree to, if you will --

18 A. Okay, sir.

19 Q. -- it's no indication whatever that this came from
20 France?

21 MR. LOUIS: Objection. This question has been asked
22 and answered previously.

23 THE COURT: Overruled. You can answer it one more
24 time.

25 A. I can't conclude where it came from just based upon the

1 language on the box.

2 BY MR. AMANN:

3 Q. All right. You cannot conclude; right?

4 And if this product was coming to be -- or had to be
5 repackaged for distribution in the United States, it certainly
6 would make sense, wouldn't it, sir, that you would receive
7 pills on the one hand and then the packaging on the other,
8 wouldn't it, because it has to be packaged to suit the U.S.
9 market?

10 A. If it's going to be repackaged to the U.S. market, why
11 would they even send me the French packaging, sir? I can't
12 understand that.

13 Q. Okay. You can't understand that. And one of the reasons
14 you can't understand it is that if Mr. Xu had the ability to
15 print anything he wanted, what you can't is, why would he send
16 you packaging that was clearly marked in French?

17 A. Is that a question or a statement, sir?

18 Q. That's confounding to you, isn't it?

19 A. Is that a question or a statement, sir?

20 Q. Is that confounding to you?

21 A. No, it's not.

22 Q. That doesn't make sense to you?

23 A. No. It's --

24 Q. I'm not trying to play lawyering games.

25 THE WITNESS: I don't want to confuse it. There's a

1 question in there on what it is, Your Honor.

2 BY MR. AMANN:

3 Q. Well, then you just tell me to fix it and I'll try to.

4 A. Please fix it.

5 Q. If Mr. Xu had the ability to print anything he wanted, it
6 is that fact -- if you assume that fact -- and you're assuming
7 that fact, aren't you?

8 A. Based upon statements he made to me that he had ability
9 to, yes.

10 Q. Because of statements he made --

11 A. Yes, sir.

12 Q. -- you're assuming that fact. It is inconsistent for him
13 to have mailed you something that was in French packaging,
14 isn't it, that fact alone is inconsistent with his ability to
15 produce U.S. packaging. That's the question.

16 A. No, it's not.

17 Q. Okay. You disagree with me?

18 A. And I can explain.

19 Q. Go ahead.

20 A. These were representative samples. These are the early
21 stages of negotiations. As agents of the United States
22 Government we have a dilemma. If he was going to make a copy
23 of an American packaging and wanted us to provide it, we could
24 not provide him legitimate packaging because we would be
25 facilitating a crime and they would be able to produce that

1 packaging after the fact.

2 Q. So what you're saying then is that Government can't
3 facilitate crime; right?

4 A. No, we cannot facilitate a crime.

5 Q. All right. Did you give Mr. Xu \$5,000 to send you this
6 stuff?

7 A. Yes, we did.

8 Q. In your opinion it was crime; right?

9 A. Yes, it was.

10 Q. That facilitated the commission of a crime, didn't it?

11 A. That was a criminal investigation, no, it did not. He
12 was committing a crime.

13 Q. Did you help facilitate the commission of a crime by
14 giving him 5,000 plus dollars so he would send you product?

15 MR. LOUIS: Objection. Argumentative.

16 THE COURT: Overruled.

17 A. We paid him for receipt of the counterfeit merchandise so
18 we could ascertain whether it was, indeed, counterfeit.

19 BY MR. AMANN:

20 Q. Yes or no?

21 THE COURT: He's answered the question.

22 MR. AMANN: Thank you.

23 BY MR. AMANN:

24 Q. Another shipment, 28-B, Plavix.

25 A. Yes, sir.

1 Q. The pills are in the box; right?

2 A. Yes, sir.

3 Q. The box is in French; right?

4 A. Yes, sir, that's correct.

5 Q. Do we have examples, sir, of any product not coming from
6 France?

7 A. I believe the Tamiflu had English writing on it. I would
8 have to look through all the exhibits.

9 MR. AMANN: Maybe the Government can help us out over
10 here.

11 BY MR. AMANN:

12 Q. While Mr. Lewis is working or helping me find that, one,
13 two, three, four, five, six, seven, eight shipments of
14 product; right?

15 A. Yes.

16 Q. Out of those eight shipments of product, how many were in
17 French and how many were in English? You can check your log
18 please, sir.

19 A. I would have to look at the individual -- I believe the
20 only one that was in English was the Tamiflu, but that was
21 after the box -- I'd have to get down and look at the
22 exhibits, if you want me to do that.

23 Q. Sure.

24 MR. AMANN: With the Court's permission.

25 THE COURT: We'll take our recess a little bit early

1 so we don't waste the jury's time while he's looking at
2 exhibits.

3 Let's take a 15-minute recess, ladies and gentlemen.

4 (There was a recess taken.)

5 (Outside the presence of the jury.)

6 THE COURT: Here are copies of the proposed charge.

7 MR. AMANN: May I approach.

8 THE COURT: Yes, I don't want to have to toss them to
9 you.

10 Look over them. At the end of the day I'll entertain
11 any objections you have. I know the evidence hasn't
12 concluded. I think the element that the defense wants on the
13 third construction is adequately covered by the definition of
14 counterfeit mark, which requires that its use likely confuse,
15 cause mistake or deceive, so I'm not giving the fifth element
16 requested by the defendant on Counts 5 through 9.

17 MR. AMANN: Judge, with respect to the definition of
18 "counterfeit," that comes right out of the statute. We had
19 requested that itself is the --

20 THE COURT: Yes. We're going to have the objections
21 later today.

22 MR. AMANN: Okay. I'm sorry.

23 THE COURT: Where is Mr. Xu?

24 MS. KETTERMAN: They took him back.

25 THE COURT: We'll just wait for him.

1 Do you have your next witness available?

2 MR. LOUIS: Yes, Your Honor, I do.

3 (Jury comes in.)

4 THE COURT: Be seated, please Mr. Amann, you may
5 conclude.

6 MR. AMANN: Thank you, Your Honor.

7 BY MR. AMANN:

8 Q. Before the break I believe you said that Tamiflu that was
9 sent to you by Kevin was in English. We have, during the
10 break, tried to gather up all of the Tamiflu that was sent to
11 you. I want you to look at it, if you would please.

12 A. Yes, sir.

13 Q. Okay. Is that one of them?

14 A. Yes, it is.

15 Q. Can you pull that one out?

16 Are all of these going to be the same?

17 A. Yes, they're all the same.

18 Q. Can we open -- are all of these without -- I'm not going
19 to go through every exhibit, try to make things easier -- with
20 respect to all of the Tamiflu that was sent to you, you're
21 claim is that it was in English; right?

22 A. That was what I believe, yes.

23 MR. AMANN: All right. Judge, may I use the Elmo?

24 THE COURT: Sure.

25 MR. AMANN: Thank you.

1 BY MR. AMANN:

2 Q. Okay. This is the Tamiflu that we're talking about;
3 right?

4 A. Yes, sir.

5 Q. And that's -- the one I've got here up on the Elmo now,
6 that's how every single one of these Tamiflus --

7 A. Yes.

8 Q. -- in the various exhibits looked; right?

9 A. Yes.

10 Q. Now, on the back we have the word "Tamiflu"; right?

11 A. That's correct.

12 Q. All right. Tamiflu's going to be spelled the same way in
13 English, French, it is what it is, Tamiflu; right?

14 A. Yes.

15 Q. All right. And Roche at the top there, R-o-c-h-e, are
16 those the people that make Tamiflu?

17 A. Yes, that's correct.

18 Q. All right. Their name is going to be spelled the same in
19 French, English, German, Italian; right?

20 A. That's correct.

21 Q. All right. Now, below the Tamiflu, we have the word that
22 I'm hesitant to try to pronounce, oseltamivir, is that the
23 chemical name for Tamiflu?

24 A. That's correct.

25 Q. All right. And that's a peculiar chemical name that just

1 describes that particular drug, isn't it?

2 A. That's correct.

3 Q. All right. And that's going to be spelled the same way
4 in French, English, German, Italian, isn't it?

5 A. That's correct.

6 Q. All of this Tamiflu we're talking about could well have
7 come from the European market; right?

8 If I put these back into a particular bag --

9 A. Are you speaking hypothetically or these particular ones?

10 Q. These particular ones could have come from the European
11 market?

12 A. It's unlikely, but --

13 Q. These -- oh, you have one under here too.

14 A. Yeah.

15 Q. These could have come from the European market; right?

16 A. There's no indication that they have.

17 Q. There's no indication that they haven't --

18 A. Yes, there are.

19 Q. -- based on the printing?

20 A. Based -- if you want to limit it to just the printing?

21 Q. Yes, I want to limit it to how it showed up when you got
22 it.

23 A. Based on the printing, it could have come from anywhere.

24 MR. AMANN: Okay. I'll pass the witness, Your Honor.

25 THE COURT: Anything else, Mr. Louis?

1 MR. AMANN: May I return these?

2 THE COURT: No, I take it by your silence.

3 All right. Call your next witness.

4 MR. LOUIS: Next witness is Mike Dalton.

5 THE WITNESS: May I return to my seat?

6 THE COURT: Sure.

7 THE WITNESS: Thank you, Your Honor.

8 THE COURT: Please come around, sir, and be sworn as
9 a witness.

10 MICHAEL DALTON

11 having been first duly sworn, testified as follows:

12 THE COURT: Be seated, please.

13 Mr. Louis, you may proceed.

14 MR. LOUIS: Thank you, Your Honor.

15 DIRECT EXAMINATION

16 BY MR. LOUIS:

17 Q. Please state your name and spell your last name for the
18 benefit of the ladies and gentlemen of the jury.

19 A. Michael Patrick Dalton, D-a-l-t-o-n.

20 Q. How are you employed, Mr. Dalton?

21 A. I work for Eli Lilly Company, a pharmaceutical company in
22 Indianapolis, Indiana.

23 Q. What's your position with Eli Lillie?

24 A. I'm the team leader of the global product protection
25 technical team.

1 Q. And what does that mean? What does a team leader do?

2 A. I supervise the group who conducts all of the physical
3 and chemical analysis on all of the suspect products that are
4 submitted to my laboratory for analysis.

5 Q. Does that mean that you have some background in
6 chemistry?

7 A. I do.

8 Q. Would you please tell the ladies and gentlemen of the
9 jury what your background is in chemistry?

10 A. From an education standpoint my college degree is a
11 bachelor of science in biology and I have a minor in
12 chemistry. I've also worked at Lilly as a -- in the
13 laboratory performing chemical analysis as well.

14 Q. And how long have you done that for Eli Lilly?

15 A. I've worked for Lilly for 16 years.

16 Q. Prior to joining Lilly, did you work in any other
17 capacity as a chemist or in the field of chemistry?

18 A. Prior to working at Lilly?

19 Q. Yes. Did you have any other employment?

20 A. No, I've worked at Lilly my entire career.

21 Q. All right. Now, did -- in your capacity as a team
22 leader, do you have an occasion to receive samples from
23 outside sources to determine whether or not a sample product
24 or trademark product is authentic or counterfeit.

25 A. Yes, I do.

1 Q. Do you do that on few or many occasions?

2 A. Very many occasions.

3 Q. Did you receive, in connection with this case, certain
4 samples to conduct an analysis?

5 A. Yes, sir.

6 Q. Did you, in fact, conduct an analysis?

7 A. I was a part of conducting the analysis, yes.

8 Q. All right. I've got several exhibits. Let me go in
9 order. Let me first hand you what I have marked as
10 Government's Exhibit No. 52 and ask you to look at that
11 exhibit. And are you familiar with that exhibit?

12 A. Yes, I am.

13 Q. And did you conduct an analysis of that exhibit?

14 A. Yes, sir.

15 Q. Did you write a report of your analysis of that exhibit?

16 A. Yes, sir.

17 Q. For the record, what is in Government's Exhibit No. 52?

18 A. There is a blister card containing seven tablets and a
19 carton and a package insert.

20 Q. All right. Do you have some -- what's called a log that
21 references a case number that would indicate who submitted the
22 sample to you?

23 A. Yes.

24 Q. And can you tell us what number's associated with the
25 case number?

1 A. The ICE number is 2866085.

2 Q. All right. Now, once a sample is submitted to Eli Lilly
3 for analysis, what's the first thing that happens?

4 A. Well, the first thing we do is we establish chain of
5 custody. So we will evaluate what is submitted to us and make
6 sure that all of the contents and counts of the tablets are
7 accurate. We will then log that sample into our database so
8 that we have a record of that sample. We will record basic
9 information during our initial visual analysis of that
10 product. We will evaluate what questions are being asked
11 about that product from the submitter, whether it's for
12 authenticity or to determine what the chemical composition of
13 the product is. We will develop a protocol to analyze the
14 product to answer those questions, execute that protocol,
15 evaluate the data, verify it and write a report and submit
16 that back to the submitter of the sample.

17 Q. All right. And have you identified that as a sample that
18 you examined and did analysis of?

19 A. Yes, sir.

20 Q. Did you provide that yesterday or the day before to me
21 when you arrived?

22 A. Yes.

23 MR. LOUIS: At this time I move for the admission of
24 Government's Exhibit No. 52.

25 MR. AMANN: Just one quick question, Your Honor, if I

1 can.

2 Are there -- do you have some initials on here that
3 show you're the one that did the analysis and so forth? Is
4 There some kind of marking I can look for?

5 THE WITNESS: The sample number is referenced here
6 and it is also referenced on the report --

7 MR. AMANN: Oh, okay.

8 THE WITNESS: -- that's generated. That's --

9 MR. AMANN: And you match up the numbers.

10 THE WITNESS: Yes, sir.

11 MR. AMANN: Okay. I have no objection, Your Honor.

12 THE COURT: All right. Government's Exhibit 52 is
13 admitted.

14 BY MR. LOUIS:

15 Q. Now, if you could go ahead and open Government's 52 and
16 when you received this, tell the ladies and gentlemen of the
17 jury what it is that you received that's Government's
18 Exhibit 52.

19 A. I have a carton labeled as Zyprexa 10 milligrams.
20 There's a patient leaflet or insert. And there is a blister
21 card containing seven tablets also labeled an a Zyprexa 10
22 milligrams.

23 Q. All right. And what's the first -- one of the first
24 things that you did in reference to doing your examination?

25 A. One of the first things we typically do is look at the

1 batch numbers that are on the packaging through our batch
2 number database. And the batch number on the carton, which is
3 A202503 was indicated early on to not be a Zyprexa
4 10-milligram batch number assigned by Lilly. It is --

5 Q. Say that one more time slower.

6 A. Okay. The batch number on the carton, which is --

7 Q. Where is that batch number located?

8 A. It is stamped or imprinted here on the end of the carton.

9 Q. I'm going to show you what's been already marked and
10 admitted into evidence as Government's Exhibit 60, Photograph
11 No. 26. Is this what you are looking at right now?

12 A. That is a different batch number than what I'm looking
13 at.

14 Q. Different batch number. What's the batch number you have
15 there?

16 A. 202503.

17 Q. Okay. Looking at this batch number -- now, where is the
18 batch number?

19 A. It's right next to the word "lot."

20 Q. Okay. So is lot and batch the same thing?

21 A. Lot and batch are synonymous, yes.

22 Q. Okay. And the number there, if I can read it and
23 highlight it, is 202503; is that right?

24 A. The letter "A" is the prefix there.

25 Q. Now, you said that was not associated with what?

1 A. That is a batch number when we did the search in our
2 batch numbering database at Lilly that is associated with a
3 5-milligram Zyprexa. It is a valid Zyprexa batch number, but
4 for 5 milligrams, not 10 milligrams.

5 Q. So it is -- so that's one indication that this may not be
6 a Eli Lilly product because it's got the wrong batch number
7 for the wrong milligram?

8 A. Correct.

9 Q. Anything else that you can tell us that you looked at
10 that was of some concern?

11 A. There were other observations made about the printing
12 quality by the packaging experts. The -- some of the fonts
13 were not consistent with Lilly printing practices. There
14 are -- there's a printer's mark on the -- one of the flaps.

15 Q. Okay. I'm going to turn it and you can tell me which
16 one.

17 A. Slide down, if you would please. Can you flip that over?

18 Q. All right.

19 A. Flip the carton on the other side.

20 Q. Like this?

21 A. No, the --

22 THE COURT: Turn it over.

23 A. Turn it over. There you go. Yeah, right there where it
24 says "FB" on the bottom right side of the screen, that is the
25 printer's mark that is put on there by the company who

1 actually prints the cartons. And that was inaccurate as far
2 as the design. The board stock was also something that the
3 packaging experts noticed was not consistent with the board
4 stock, the thickness and weight of the board paper that we
5 use.

6 BY MR. LOUIS:

7 Q. All right. So visual inspection of a carton raises some
8 concerns that you've indicated. What's the next thing that
9 was examined and looked at to determine whether it's authentic
10 or counterfeit?

11 A. Well, the next thing we looked at was the blister card.
12 Again, looking at the batch number first, the batch number in
13 this case is a valid Zyprexa 10-milligram batch number. So
14 that was accurate. However --

15 Q. Let me stop you. Are you telling me the batch number on
16 the carton and the batch number on the actual foil is
17 different?

18 A. Yes.

19 Q. And just quickly, if I can see here, do I have it the
20 right way, right side or different side? Should it go the
21 other way?

22 A. Yeah, that's the correct side. It should be the correct
23 side.

24 Q. Okay. I don't know if I'm going to be able to do any
25 better than that. But why don't you just read it for us so

1 it's in the record.

2 A. Okay. The batch number on the blister is A229505
3 imprinted here and an expiration day of 03-2009.

4 Q. All right. So hold on right there. Read that for us one
5 more time on the blister foil?

6 A. On the blister foil, A229505.

7 Q. And do you see that on this exhibit I have on this Elmo
8 screen, which is 60 -- which is Picture No. 26, do you see
9 that?

10 A. Yes, sir.

11 Q. So that's the same thing that's on that blister foil?

12 A. Correct.

13 Q. Now, after inspecting and finding that the lot number was
14 a valid lot number assigned to that milligram, what was the
15 next thing that was done?

16 A. Well, we noticed that that the batch number, although it
17 is accurate, is stamped onto the blister incorrectly. If you
18 notice on this, it is actually upside down --

19 Q. That's why I couldn't read it.

20 A. -- and backwards. So to actually read it left to right,
21 you read it from the foil side. But authentic packaging is
22 stamped on the printed side and it's read left to right
23 looking at it from this side.

24 Q. All right. So the positioning of the batch number is
25 incorrect on the blister foil?

1 A. That's correct.

2 Q. What's the next thing that was done in connection with
3 the analysis of the packaging and the sample?

4 A. We also looked at the package insert and, again, there
5 were differences in printing that were observed in the stock
6 of the paper.

7 Q. All right. Now, with respect to the chemical analyses,
8 what's the first type of analysis that's done?

9 A. As far as Zyprexa, the first thing we do would be a
10 visual analysis of the tablets before we would chemically
11 analyze it to make sure the tablets look consistent with
12 authentic. And then we would proceed with the chemical
13 analysis.

14 Q. With respect to this particular sample, was it consistent
15 or not?

16 A. From a physical standpoint?

17 Q. Yes.

18 A. Physically, no. The tablets were kind of creme color,
19 off white color. Authentic Zyprexa tablets are white. The
20 imprint on the tablets was also of poor quality, and in some
21 cases, a different color of ink for the imprint than authentic
22 tablets.

23 Q. All right. Now, during -- conducting the chemical
24 analyses itself, what's the first test that you do and, would
25 you tell the ladies and gentlemen of the jury, why you do this

1 test?

2 A. Okay. For Zyprexa there were two chemical analysis that
3 we conducted. One was a potency analysis to determine what
4 the potency of the active ingredient was. The second analysis
5 was an impurity analysis so that we could assess what
6 degradation products and impurities were present that we would
7 typically see in authentic Lilly manufactured material. And
8 both of those analysis are conducted using what's called an
9 HPLC or high performance liquid chromatography, common
10 laboratory instrument in most labs.

11 Q. How expensive, if you know, is an HPLC machine or
12 equipment?

13 A. They can vary, but from my experience it's anywhere from
14 80 to \$100,000 is probably a common range. There's many
15 different types and models and manufacturers. So 80 to 100 is
16 what I've experience that my laboratory has actually
17 purchased.

18 Q. Now, did -- what was the result of the HPLC test that was
19 done on this sample, Government's Exhibit 52?

20 A. I don't have the report in front of me, but I do recall
21 that each -- I don't know the exact potency value in front of
22 me for this one.

23 Q. Let me hand you a document --

24 A. Thank you.

25 Q. -- and see if that purports to be your report.

1 A. Yes. Based on the potency analysis, the result was that
2 this was a subpotent tablet. The result was 8.2 milligrams
3 per tablet. And this was a 10-milligram tablet. Lilly has
4 established specifications in the United States that our
5 tablets must meet and that is 9.2 to 10.5 milligrams per
6 tablet.

7 Q. And that's established because that's the information
8 that's provided to the Food and Drug Administration in being
9 able to get this tablet, Zyprexa, being able to manufacture
10 and market it.

11 A. Correct, that's a registered commitment.

12 Q. So it's subpotent. What about any impurities?

13 A. Yes, we also analyzed it for the related substances or
14 impurity profile. And in this particular case it did also
15 fail the largest individual which means that as we're
16 evaluating the impurity profile, there cannot be one impurity
17 that is above a certain threshold. And our limit for that, I
18 believe, is .5 percent. And in this case -- I'm sorry, not
19 more than 2 percent is what I have here. And the largest
20 individual is .84 so it was four times the regulatory
21 commitment there. Aside from that, there were impurities and
22 other components present that are not typically seen in
23 authentic Lilly manufactured material.

24 Q. Does that mean -- are you able to, when you do these
25 tests, isolate and indicate what those impurities are or not?

1 A. We are capable, but we did not do that for these samples.

2 Q. Okay. Now, during the visual inspection, if you took an
3 authentic sample and a sample that you've identified as
4 counterfeit based on your analysis, and did a side-by-side
5 comparison, could someone who's not as knowledgeable as you
6 know which one is authentic and which one is not?

7 A. I suppose if the differences are extreme enough someone
8 would notice there's a difference. But if someone did not
9 have prior knowledge of Lilly manufactured Zyprexa at all the
10 various manufacturing sites that we have around the world, one
11 would not know the variability seen in our own product that is
12 within acceptable limits. But in looking at the suspect
13 sample against the controlled sample used here, there are
14 obvious differences that somebody would notice.

15 Q. All right. Now, did you record those in your report?

16 A. Yes.

17 Q. Okay. And do you have a nice graph of that as part of
18 Page 2 of your report?

19 A. Yes.

20 Q. All right. I'm going to mark that as part of
21 Government's Exhibit, which I'm going to offer later,
22 Government's Exhibit 52-A. Right now let me hand you what
23 I've marked as Government's Exhibit No. 52-A and ask you to
24 look at these and see if there's an excerpt from all of the
25 analysis that you performed in the reports of those analysis?

1 A. I believe there was one more.

2 Q. All right.

3 A. 2319.

4 Q. I'll have to find that one.

5 A. Okay.

6 Q. 2319?

7 A. Yes, sir.

8 Q. Take a look and see if that's the report you're
9 referencing?

10 A. Yes.

11 MR. LOUIS: All right. At this time I'm going to
12 offer Government's Exhibit 52-A.

13 MR. AMANN: I have no objection, Your Honor.

14 THE COURT: You'd better clip all of that together so
15 we can keep it --

16 MR. LOUIS: I'm going to staple it. I'll put a paper
17 clip on it right now.

18 THE COURT: Okay. 52-A is admitted.

19 BY MR. LOUIS:

20 Q. All right. Looking at the report, this outlines the
21 packaging and then the comparison of the pills; is that right?

22 A. Yes, sir.

23 Q. And it's hard to kind of see on this one, but you're
24 saying there was a substantial difference in appearance?

25 A. There was a difference in appearance compared with the

1 authentic, yes. It was an off white to cream-colored tablet.
2 And it's difficult to see there, but the print quality of the
3 imprint on the tablet, which were a 10-milligram tablet is
4 Lilly, L-i-l-l-y, in all capital letters 4117, which is the
5 item code, but there was differences.

6 Q. All right. And your conclusion was that the packaging
7 and the actual tablet or the pill was what?

8 A. That they were not authentic.

9 Q. Okay. Now, let's look at the next sample, which I have
10 marked as Government's Exhibit -- part of Government's
11 Exhibit 52 as well. Tell us if this sample was received at
12 the same time as you received what I've already marked as
13 Government's Exhibit 52.

14 A. They were received within a couple of weeks of each
15 other.

16 Q. Were they tested at the same time or do you know?

17 A. That, I don't know if they were tested on the exact same
18 sample run or not but close in proximity.

19 Q. Is this the sample that you did the testing on?

20 A. Yes.

21 MR. LOUIS: I think I'm going to mark this as a
22 different one. I'm going to mark this as Government's
23 Exhibit 52-I.

24 THE COURT: 52-I.

25 MR. LOUIS: I have some others that I've already

1 marked.

2 THE COURT: I don't have them on your exhibit list.

3 MR. LOUIS: I'll do a revised exhibit list, Your

4 Honor.

5 BY MR. LOUIS:

6 Q. So for the record, again, this is a sample that you did

7 the analysis on?

8 A. Yes.

9 MR. LOUIS: At this time I offer Government's

10 Exhibit 52-I.

11 MR. AMANN: I have just one question, Your Honor.

12 These markings right there, did you make those?

13 THE WITNESS: No.

14 MR. AMANN: Do you know who made those markings?

15 THE WITNESS: I do not know.

16 MR. AMANN: Are those markings that would have been
17 made at the time the stuff was packaged or does that look like
18 the marking was made after it was packaged?

19 THE WITNESS: It would be a mark after it's been
20 packaged. I've seen marks like that on -- being submitted to
21 us before. Sometimes agents or investigators from our side
22 will sign off.

23 MR. AMANN: Okay. I have no objection.

24 THE COURT: 52-I is admitted.

25

1 BY MR. LOUIS:

2 Q. And now we're going to go through the same with respect
3 to this particular packaging. Can you read the batch number
4 for us?

5 A. Sure. It is -- the batch number on the carton is
6 A202503.

7 Q. Is that consistent or inconsistent with that particular
8 milligram of Zyprexa?

9 A. It is, again, the 5 milligram, not the 10 milligrams as
10 indicated on the carton.

11 Q. All right. And then just looking at the actual chemical
12 analysis that was performed of this sample -- well, first of
13 all, was the imprint of the batch number on the sealed foil,
14 was it positioned correctly or incorrectly?

15 A. Incorrect. This particular foil is similar to the prior
16 sample. It's A229505. So they do not match. And, again,
17 it's in the incorrect orientation.

18 Q. All right. Did you also do the same type of test that
19 you mentioned earlier?

20 A. Yes.

21 Q. HPLC test?

22 A. Yes, sir.

23 Q. Any other test that you performed?

24 A. No. Identical process.

25 Q. With respect to this sample, did you also prepare a

1 report that corresponds to that sample, which is -- you have
2 ID No. 2319?

3 A. Yes, sir.

4 Q. And it says Lilly product and has Zyprexa. What's that
5 little symbol that's next to Zyprexa?

6 A. The registered trademark symbol.

7 Q. Now, on this one you did a larger scale of the comparison
8 of the pill; right?

9 A. Yes.

10 Q. Is that the differences that you were talking about?

11 A. Yes, you can see in the upper left-hand quadrant the
12 imprint on the tablet should be, as you can see on the right
13 hand, the authentic Zyprexa table, Lilly 4117, and that is the
14 imprint on one side in blue ink. You can see it's a faint --
15 more faint imprint on the left and some of the letters are
16 smudged.

17 Q. Now, could that simply be caused because the pill has
18 been degraded? Could it have been authentic and the pill has
19 just simply been degraded by handling?

20 A. It's not typically seen. There is some variation in the
21 Lilly process itself when you see that. However, that is an
22 extreme case of where it's not consistent with what we've seen
23 in our process.

24 Q. And then based upon the HPLC test, what were your
25 findings as to whether or not it contained -- what it said it

1 contained?

2 A. I believe -- and, again, if I can see the report it would
3 be helpful.

4 Q. Sure. First of all, is this your report?

5 A. Thank you. Yes, it is.

6 Q. Minus the page that's on the screen?

7 A. Minus the page on the screen. The product was confirmed
8 to contain olanzapine, the active ingredient in Lilly's
9 Zyprexa, but both the packaging component and tablets were
10 determined to be non-authentic.

11 Q. All right. And I believe you have that in this -- on
12 this page; is that right?

13 A. Yes, the potency value in this case was 7.54 milligrams
14 per tablet.

15 Q. And what is the acceptable range?

16 A. The U.S. regulatory limits are 9.20 to 10.50 milligrams
17 per tablet. So it's approximately 75 percent potent.

18 Q. And any impurities that were found?

19 A. Yes, the related substances or impurities were 1.64
20 percent. I believe the registered limits are not more than
21 1.5 percent. And, again, the largest individual, 1.8 -- or
22 1.08, so significantly elevated.

23 Q. All right. Let's move on to -- let me hand you what's
24 marked as Government's Exhibit No. 52-B and ask you to take a
25 look at this sample and first identify what is the drug that's

1 part of the sample?

2 A. Again, it Zyprexa.

3 Q. Did you do an analysis of this sample?

4 A. Yes, sir.

5 Q. Did you bring that with you when you traveled to Houston?

6 A. Yes, sir.

7 Q. And the same analysis of this sample that you did with
8 two previous samples?

9 A. Everything's identical. The batch number on the carton
10 is identical as the previous two and the batch number on the
11 foil is identical.

12 MR. LOUIS: At this time I'd move for the admission
13 of Government's Exhibit No. 52-B.

14 MR. AMANN: No objection, Your Honor.

15 THE COURT: All right. It is admitted.

16 BY MR. LOUIS:

17 Q. And looking at this particular sample, can you tell us if
18 the packaging issue or packaging batch number is the same as
19 the previous two packages that you looked at?

20 A. It is, yes.

21 Q. And did you do the same type of testing with respect to
22 the sample?

23 A. Yes.

24 Q. And let me see, that would correspond -- if you would
25 double check for me --

1 A. 2699.

2 Q. Yes. Would you see if this is a report that corresponds
3 to your analysis of that sample.

4 A. Yes.

5 Q. For time's sake, is this the summary of your report with
6 respect to this sample?

7 A. Yes.

8 Q. So you have the carton, front and back; is that correct?

9 A. Yes.

10 Q. And would you just read for the record what the batch
11 number that's on this carton.

12 A. The batch number on the carton was A202503. And the
13 batch number on the blister foil was A229505.

14 Q. All right. And then looking at this particular picture,
15 is that a better view of the pills that you were talking
16 about?

17 A. Yes.

18 Q. For the record, what is the difference between these two,
19 the reference sample and the pill that was submitted for
20 analysis?

21 A. In this case, again, the pills were an off white -- the
22 tablets were an off white color, similar to the prior samples.
23 The imprint quality on this tablet is better than the prior
24 two, however, the color of the imprint is a much darker ink, a
25 dark blue to a black colored ink as compared with the blue

1 imprint of Lilly 4117 in the authentic tablets photo.

2 Q. And now, what was the potency of this sample that you
3 analyzed?

4 A. 7.25 milligrams per tablet.

5 Q. Again, subpotent?

6 A. Yes, sir.

7 Q. As far as the impurities, what did you determine?

8 A. The, again, the largest individual impurity exceeded the
9 limit of not more than .2 percent. It was .73 percent. In
10 this case the related substances did meet the specifications.
11 However, there were impurities present that are not typically
12 observed in authentic Lilly product.

13 Q. All right. Okay. Let's look at the next exhibit that's
14 marked Government's Exhibit 52-C. And, again, is this a
15 sample of Zyprexa carton and the pill that you conducted an
16 analysis?

17 A. Yes, sir.

18 Q. Did you bring that with you today when you traveled --

19 A. Yes, sir.

20 Q. -- to Houston?

21 A. Yes, sir.

22 MR. LOUIS: At this time I move for the admission of
23 Government's Exhibit 52-C.

24 THE COURT: "C" as in Charles?

25 MR. LOUIS: "C" as in Charles.

1 MR. AMANN: If I may have a moment, Judge, I think
2 there's a bag inside a bag. I just want to --

3 Sir, this -- what's marked as Government's 52-C is a
4 bag and inside it is a bag and there's something inside that
5 bag. Is that all --

6 THE WITNESS: That's the original evidence bag that
7 the sample was sent in.

8 MR. AMANN: Okay. So it's the original evidence bag
9 that you put it in.

10 THE WITNESS: Correct.

11 MR. AMANN: Okay. I have no objection to 52-C.

12 THE COURT: It's admitted.

13 BY MR. LOUIS:

14 Q. Again, with respect to 52-C, would you read what the
15 batch number is on the carton.

16 A. A202503.

17 Q. Is that the same batch number for the other cartons that
18 you've inspected?

19 A. Yes.

20 Q. All right. Then looking at the summary of your report
21 that's on the screen, is this a sort of, like, a caption of
22 all the tests that you performed that has ID -- I'm sorry,
23 2730?

24 A. Yes.

25 Q. And that's the sample you have there, 2730?

1 A. Correct.

2 Q. And, again, looking at the comparison of the pills, is
3 this the same difference that you indicated in the previous
4 sample that you looked at?

5 A. Correct?

6 Q. And just quickly for the record, what is that?

7 A. Difference in the white coloring of the tablet. It's
8 more of an off white. And, again, the color of the imprint
9 was darker than authentic.

10 Q. Was there any issues with the imprint or the writing on
11 the foil?

12 A. There is a difference with this sample from the other two
13 in that the batch number on the foil in this case is the same
14 as that on the carton. And that is the 5-milligram batch
15 number.

16 Q. Then what was the potency of this particular sample?

17 A. 6.49 milligrams per tablet.

18 Q. And then what was the impurities?

19 A. In this case the impurities did meet the United States
20 registered specifications. However, the largest individual
21 impurity exceeded the limit. And, again, the impurity profile
22 was not consistent with Lilly manufactured Zyprexa.

23 Q. All right. Now, I'm going to hand you what's marked as
24 Government's Exhibit 52-E and I'll ask you to take a look at
25 that and determine if that is a sample that you also conducted

1 an analyses.

2 A. Yes, it is.

3 Q. And is that a sample of carton Zyprexa?

4 A. It's just a single blister.

5 Q. Okay. Did you do a report of that analysis?

6 A. Yes.

7 MR. LOUIS: At this time I move for the admission of
8 Government's Exhibit No. 52-E.

9 MR. AMANN: No objection, Your Honor.

10 THE COURT: It's admitted.

11 BY MR. LOUIS:

12 Q. Looking at this sample, did you do an HPLC test?

13 A. Yes, sir.

14 Q. And looking at part of Government's Exhibit 52, is this
15 the sample that you analyzed identified --

16 A. Yes.

17 Q. -- as Sample 2731?

18 A. Yes, sir.

19 Q. All right. And then, again, is it the same difference in
20 the coloration of writing that's on the pill?

21 A. Yes.

22 Q. Based upon that, did you do an analysis of the potency?

23 A. Yes.

24 Q. And what was that?

25 A. 5.90 milligrams per tablet.

1 Q. And it's supposed to be what?

2 A. Between 9.20 and 10.50.

3 Q. Did you find any impurities that were not consistent with
4 authentic 10 milligrams Zyprexa?

5 A. Yes.

6 Q. Based upon that, did you make a determination that this
7 was counterfeit?

8 A. Yes, sir.

9 Q. I'll hand you what I marked as Government's Exhibit 52-D
10 and ask you to look at this sample and see if this is one that
11 you conducted an analysis of.

12 A. Yes, it is.

13 Q. How do you know that?

14 A. I know that because I put the samples in this bag and
15 brought them with me. And this is our sample number.

16 MR. LOUIS: At this time I move for the admission of
17 Government's Exhibit 52-D.

18 THE COURT: "D" as in delta?

19 MR. LOUIS: "D" as in delta.

20 MR. AMANN: No objection, Your Honor.

21 THE COURT: It's admitted.

22 BY MR. LOUIS:

23 Q. Looking at Government's Exhibit 52-D, did you inspect
24 packaging with respect to this exhibit?

25 A. Yes.

1 Q. And did you find the same batch number as the previous
2 cartons that you reviewed?

3 A. In this case the batch number on the carton is the same
4 as what we've seen in the blisters previously. It's A229505.
5 And that is the same batch number or the blisters. So for
6 this sample the batch number is accurate on both the carton
7 and the blisters for Zyprexa 10 milligrams.

8 Q. So that is a valid batch number for 10 milligrams?

9 A. Yes, sir.

10 Q. All right. And what's the sample ID number?

11 A. 2732.

12 Q. And is that summary of report --

13 A. Yes.

14 Q. -- of the sample that you analyzed?

15 And based upon review of the sample carton, did you
16 determine that carton to be authentic or --

17 A. Counterfeit.

18 Q. And then looking at the pill itself, did you find
19 problems with the imprint on the pill?

20 A. Obviously in the picture the imprint is complete, it's
21 off center and it's not legible completely.

22 Q. During the HPLC what was the potency of this suspect
23 sample?

24 A. 6.13 milligrams per tablet.

25 Q. Is that less than the allowed amount given the protocol

1 of FDA and Eli Lilly?

2 A. Yes.

3 Q. And what was the impurities?

4 A. In this case the related substances specifications were
5 met. However, there were impurities observed not typically
6 seen in Lilly product. So it was determined to not be Lilly
7 manufactured material.

8 Q. All right. Now, I believe this is the last one. Looking
9 at --

10 MR. LOUIS: Pass the witness.

11 THE COURT: Okay.

12 MR. AMANN: May I, Your Honor?

13 THE COURT: You may proceed.

14 MR. AMANN: Thank you.

15 CROSS-EXAMINATION

16 BY MR. AMANN:

17 Q. Mr. Dalton.

18 A. Yes, sir.

19 Q. Good morning still.

20 A. Good morning to you.

21 Q. My name is Colin Amann. I'm one of the lawyers
22 representing Kevin Xu. And I've got some questions for you
23 related to what the Government talked to you about. And I
24 want to go through the exhibits and I think you've got them up
25 there with you. Let's try to do this, try to put them

1 altogether.

2 Let's look at Government's Exhibit 52-D. Would you
3 be able, if I ask you, sir, to go in there and pull out one of
4 the packages -- one of the cartons, I should say --

5 A. Sure.

6 Q. -- and also one of the blister packs for me please.

7 A. I need scissors.

8 Q. Oh, I'm sorry.

9 Okay. Thank you very much. Now, again, for the
10 record, 52-D you've taken out of a carton that says Zyprexa;
11 right?

12 A. Yes, sir.

13 Q. And the language below the Zyprexa is obviously in
14 French, isn't it?

15 A. The --

16 Q. If you know. I mean, does that appear to be?

17 A. It is French. The purple lettering, the word olanzapine
18 directly below Zyprexa is not French.

19 Q. Okay. Is that word "olanzapine," is that way we might
20 refer to as the generic name of the drug?

21 A. Yes, the active ingredient.

22 Q. Okay. The active ingredient is olanzapine and that's
23 going to be spelled the same whether it's in English, French,
24 German or whatever?

25 A. I believe there are variations over how that is spelled

1 in some countries.

2 Q. Okay. Do you know for sure?

3 A. No.

4 Q. But that's the active -- I want to say ingredient --
5 that's the active chemical?

6 A. Correct.

7 Q. That's the chemical name. Yes?

8 A. Yes.

9 Q. Okay. And actually if we see where it's got the
10 little -- looks like a car. See where I'm talking about?

11 A. Yes.

12 Q. A car in a red triangle, do you know what that means?

13 A. I do not know.

14 Q. Have no idea. Okay. Below that it says "France."
15 Correct?

16 A. Yes.

17 Q. And it says "Lilly France SAS." What does the SAS stand
18 for, please, sir?

19 A. I do not know.

20 Q. Does Eli Lilly have manufacturing factories that
21 manufacture Zyprexa in France?

22 A. I do not believe -- no, France is not a Zyprexa
23 manufacturing facility.

24 Q. You do not have a facility in France?

25 A. We do have a facility, but it does not manufacture

1 Zyprexa.

2 Q. Does that facility market the Zyprexa?

3 A. Yes.

4 Q. You have a factory in France that doesn't make the drug,
5 but it markets the drug.

6 A. Correct.

7 Q. Do you have a facility in England, the United Kingdom
8 that -- well, let me ask you this instead of going country by
9 country and wasting time. Tell us, if you would, sir, what
10 factories in what countries do you know of where Lilly
11 manufactures the drug.

12 A. The ones that I know of are the United States, the UK,
13 and, I believe, Brazil and Mexico.

14 Q. Brazil and Mexico.

15 A. And I also believe Puerto Rico. However, the plant in
16 the UK was recently shut down so the manufacturing for that
17 has moved to, I believe, Alcobendas in Spain.

18 Q. All right. Now, with respect -- and that's where the
19 drug -- the countries where it's manufactured. Can you tell
20 us, please, sir, what countries, other than the United States
21 that Zyprexa or Eli Lilly, I should say, distributes the drug?

22 A. It's everywhere globally, multiple countries globally.

23 Q. And when we say "distribute the drug," we're talking
24 about a facility that does the packaging and so forth and then
25 sells on whatever particular market that factory is in?

1 A. I don't understand your question.

2 Q. Well, we've talked about factories that distribute in
3 other countries. I'm trying to get at what the factories --
4 they don't make the chemical, but do they make -- create the
5 packaging and then put it out for distribution?

6 A. The supply chain is very complicated from the time that
7 the tablets themselves are made at the manufacturing facility.
8 There are multiple packages and distributors globally that are
9 associated with that.

10 Q. Okay. Well, if you know, sir, you said the distribution
11 chain was pretty complicated. How complicated is it?
12 Describe what you mean by "complicated."

13 A. I can't tell you the details of every point and
14 wholesaler and packager that are associated with every
15 manufacturing site and every marketing affiliate. I have seen
16 supply chain graphs at Lilly and I do know that they are
17 complicated, that product, depending on what country the
18 tablets are going into, are packaged by different packagers.
19 The distribution chains are different in one country to
20 another. This is Lilly's top product so there is a large
21 volume of this that is distributed.

22 Q. Do you have any idea, sir, on a given year how many
23 tablets of Zyprexa Eli Lilly distributes throughout the world?

24 A. No, I don't.

25 Q. Would you be comfortable in saying it was well over

1 several million?

2 A. I think that's -- I think I could say that it's over
3 several million, but I don't know.

4 Q. This is their top seller, isn't it, worldwide?

5 A. Yes.

6 Q. So there are a lot out there?

7 A. Yes.

8 Q. All right. Now, we were talking about -- which one were
9 we on, 52, do you have that where we took these out of?

10 A. 52-D.

11 Q. 52-D. Thank you. 52-B, now, we have the Lilly Zyprexa
12 10 milligrams and these words below the 10 milligrams, are
13 those the active ingredients, again, the chemicals?

14 A. That's what I was referring to earlier when you asked me
15 about the spelling of olanzapine. In different countries it's
16 spelled differently.

17 Q. All right. So on this one, we have the different
18 spellings that would relate to the different countries?

19 A. Correct.

20 Q. So, obviously, sir, wherever this was intending to go, it
21 was intending to reach a market where if it went to France,
22 the French version of the chemical would be there; if it went
23 to England, the English version would be there; if it went to
24 Germany, you would have a German spelling. Do you see what
25 I'm getting at?

1 A. Uh-huh.

2 Q. Yes?

3 A. Yes.

4 Q. Okay. You need to have an answer for the court reporter.

5 I'm not --

6 A. I didn't know you asked me a question. I'm sorry.

7 Q. So that concludes all the various and sundry ways of
8 spelling it so no matter what country it ends up in, a person
9 would be able to look at it and understand what the chemical
10 is?

11 A. Yes.

12 Q. Okay. Now, are you familiar with the concept of parallel
13 importers. Do you know what parallel importers are?

14 A. I have heard of a parallel importer, yes.

15 Q. All right. And I'll give these back to you.

16 A. Okay.

17 Q. When -- parallel importer is somebody in the European
18 Union and in the European Union you are allowed to import
19 between the various and sundry countries without worrying
20 about the regulations of one country versus another; right?

21 MR. LOUIS: Objection. Calls for speculation unless
22 this witness has some knowledge about how that works.

23 THE COURT: Sustained.

24 BY MR. AMANN:

25 Q. Do you know?

1 A. Do I know what?

2 Q. Do you know how parallel importing works?

3 A. I know it vaguely. I've heard of it. We've been
4 involved in some cases. I do not understand the regulations
5 regarding the rules for getting it from one country to another
6 or what is required to do so.

7 Q. All right. Your vague understanding is that they are
8 allowed to go from one country to another?

9 A. That would be correct.

10 Q. Now, when a parallel distributor distributes your
11 product, isn't it true, sir, that on the batch number -- and
12 the batch number is the same as the lot number; right?

13 A. Uh-huh.

14 Q. They are required to put a prefix and that prefix they're
15 required to put on it is an "A"?

16 MR. LOUIS: Objection unless this witness has -- he
17 has established that this witness has knowledge about that
18 process.

19 THE COURT: I'll sustain the objection.

20 BY MR. AMANN:

21 Q. Do you know, sir, whether or not -- have you examined few
22 or many samples that have been sent to you?

23 A. I've examined thousands.

24 Q. Thousands. And in the course of your examination, have
25 you run across lot numbers or batch numbers that have a prefix

1 "A" to them?

2 A. Yes.

3 Q. And you certainly wanted to know what at that "A" meant,
4 didn't you?

5 A. I know what the "A" means.

6 Q. Okay. What does the "A" mean?

7 A. "A" is a prefix that's used in the batch numbering system
8 that Lilly uses to assign batch numbers. That is a letter
9 that Lilly assigns, not a parallel importer.

10 Q. All right. So your testimony is that by the assigning of
11 the "A," that was not done by somebody who repackaged it, that
12 was done by Lilly?

13 A. In this particular sample, this is a counterfeit carton
14 so Lilly did not apply this batch number to this carton.
15 However, the batch number value meaning the alpha-numeric
16 sequence and the format in which it's laid out is consistent
17 with the batch numbering system that Lilly uses.

18 Q. Okay. Does Lilly manufacture -- are you familiar with
19 examining products that have traveled throughout the European
20 Union between the various and sundry countries over there?

21 A. Yes.

22 Q. All right. And in your examination of those products, do
23 they normally or have you seen the prefix "A" on batch numbers
24 and lot numbers.

25 A. I don't always know when samples are sent to me, the

1 reasoning for why they're sent, whether it's a parallel import
2 sample, a sample that was obtained from some other source.
3 But knowing that batch number format, that is a standard
4 format used by Lilly. It is assigned through our SAP
5 database. It's used -- beginning to be used globally. That
6 is a Lilly formatted batch number.

7 Q. Does Lilly publish its batch numbers --

8 A. I do not know.

9 Q. -- to the general public?

10 A. I do not know.

11 Q. You don't know. So you just don't know if somebody could
12 find on a Lilly website or something what the batch numbers
13 were or uses, you don't know if they're published or not?

14 A. I don't know.

15 Q. All right. Now, you work at a laboratory?

16 A. Yes.

17 Q. And you talked about the high performance liquid
18 chromatography machine.

19 A. Uh-huh.

20 Q. Pretty expensive to keep, pretty sophisticated machine.

21 A. Yes.

22 Q. And you use that machine to verify whether or not what is
23 submitted to you is real?

24 A. Correct.

25 Q. Because if you have a blister pack, such as one that I've

1 taken out of Government's Exhibit 52-D, the only way to figure
2 out what's in here is to pop it out and put it in the HPLC;
3 right?

4 A. Correct.

5 Q. All right. Now, on these blister packs for Zyprexa, you
6 can't see the pill through the blister packs, can you? Right?

7 A. Correct.

8 Q. You have to actually pop the pill out and then you pop
9 out your reference pill and then you look at them side by
10 side?

11 A. Correct.

12 Q. All right. Do you have -- I guess in your report you
13 have done that for us. And I want to show the jury an
14 example. In 52-A you've got the suspect sample on the left
15 and then the authentic on the right; correct?

16 A. Correct.

17 Q. Now, do you have that actual blister pack up there or
18 these pills up there with you? Can we take them out and look
19 at them because here's what I want to do, Mr. Dalton: On the
20 Elmo these things are magnified. And I want to know -- I want
21 to see what they look like if I were just looking at them
22 without being magnified.

23 MR. LOUIS: Your Honor, I would object to any
24 tampering with an exhibit that's already been admitted in its
25 form.

1 MR. AMANN: Judge, may I respond briefly?

2 THE COURT: Sure.

3 MR. AMANN: Judge, what I want to do is publish to
4 the jury what they look like to the naked eye and not through
5 some kind of electronic enhancement.

6 THE COURT: Well, they'll see the photographs. The
7 exhibits -- they won't have the Elmo in the jury room.

8 MR. AMANN: Okay.

9 THE COURT: They're not going to be electronically
10 enhanced.

11 MR. AMANN: All right. That's the only thing I was
12 getting at, Judge.

13 BY MR. AMANN:

14 Q. I believe you testified earlier that -- well, how much
15 training do you have or how many years of training do you have
16 in differentiating between what is real and what is not real?

17 A. I've worked at Lilly for 16 years. Nine of those years
18 have been involved in the product protection and the intake
19 counterfeiting initiative so pretty much every sample -- every
20 sample that's come through in the past nine years I've been
21 involved with in some way.

22 Q. Somebody has trained you how to do it?

23 A. There has been training involved. And some of it has
24 been on-the-job experience and learning and developing the
25 skills to identify what's consistent with and not consistent

1 with authentic.

2 Q. And there is certainly a level of sophistication that
3 goes along with that training; true?

4 A. True.

5 Q. The average person may be able to differentiate between
6 what is real and not real and maybe not?

7 A. Correct.

8 Q. Fair statement?

9 A. Fair.

10 Q. And certainly if you don't have something to compare it
11 to, your job would be very hard to do indeed, wouldn't it?

12 A. Yes.

13 Q. You need to have that reference sample to make sure that
14 your comparison is valid, is that a fair statement?

15 A. I think in some cases even if you had a comparison it
16 would be difficult.

17 Q. Okay. Even with the comparison it would be difficult?

18 A. Right.

19 Q. Now, you talked about these pills, when you did the
20 analysis they met specifications in the United States market.
21 Is There any -- or are there any different specifications for
22 what those prescriptions have to contain in other European
23 markets?

24 A. Yes.

25 Q. All right. So if -- and you just did an analysis based

1 on what's applicable in the United States?

2 A. Our standard process is to utilize the specifications in
3 the country in which the product was obtained. And these were
4 obtained in the U.S. so that is the specification that we
5 applied it to.

6 Q. Do you know, sir, what specifications apply in -- let's
7 use the country France because this packaging is in French?

8 A. I don't know the exact specifications.

9 Q. So when you do the chemical analysis, you don't know --
10 you can't compare it to what specifications are allowed for in
11 France; right?

12 A. I can.

13 Q. You can, but you didn't in this case?

14 A. We did not. However, I can say that I'm certain that the
15 subpotent values on these did not meet the specifications.
16 And when I say that I don't know the exact specifications,
17 they don't shift by much. But in the United States, I
18 mentioned earlier, the potency spec was ninety-two to ten
19 point five. Another country might be ninety-five to a hundred
20 and five. So the variabilities are just a couple of
21 percentages either way. I don't know why that is, but in each
22 of these cases the potency values would not have met the
23 specifications of any other country anyway, no matter what
24 country, correct.

25 Q. That certainly is fair. Are you familiar with how Eli

1 Lilly conducts their quality control management in France, for
2 example.

3 A. I worked in the quality control laboratories for six
4 years. But I've never been to Lilly France. We all follow
5 the same quality systems, but I'm not familiar with the France
6 affiliate.

7 Q. In your quality control laboratory, would it be fair to
8 say that it's a pretty sophisticated laboratory that takes a
9 lot of personnel and a lot of money to run and maintain?

10 A. Yes.

11 Q. If you have any personal knowledge, do you know about how
12 much money on a yearly basis?

13 A. It's kind of a vague question. Are you referring to one
14 site, globally, all the quality control laboratories?

15 Q. Just pick America, for example. Let's narrow it down.

16 MR. LOUIS: Objection. That assumes the witness has
17 financial knowledge of --

18 THE COURT: Do you know the answer?

19 THE WITNESS: No, I don't know the exact number.

20 THE COURT: Move along.

21 MR. AMANN: Thank you, Judge.

22 BY MR. AMANN:

23 Q. On one of the cartons we had we determined -- I think you
24 showed us -- and I don't know if this is -- maybe you can show
25 me on this one where there's a printer's mark that identifies

1 the company that did the printing.

2 A. Here.

3 Q. Okay. Again, we're talking out of --

4 A. 52-D.

5 Q. -- 52-D. Thank you. A carton of Zyprexa out of 52-D,
6 and that little mark there is a printer's mark. And a
7 printer's mark is a mark that's unique to every printer. That
8 basically tells the world, I'm the company that did that
9 printing; correct?

10 A. Correct.

11 Q. And you can look up those marks and find out who did the
12 printing -- those are registered; right?

13 A. That, I don't know.

14 Q. You don't know. Did you make, or anybody that you know
15 of, make any attempt to try to corollate or match that
16 printer's mark to determine where these cartons had been
17 printed?

18 A. I believe the "FB" stands for Field Boxmore.

19 Q. I'm sorry?

20 A. Field Boxmore, I believe.

21 Q. Field Boxmore. What is Field Boxmore, sir?

22 A. The printer.

23 Q. Are they -- it's a company then -- are they global?

24 A. I don't know.

25 Q. All right. When you examined these samples -- and I tell

1 you what, let's put these back so we don't get them all over
2 the place. When you received, let's see, 52-D, the -- you
3 received it just like this, this is the evidence bag it came
4 in and -- or didn't come in, you obviously had to open
5 something to do the examination -- but is that a fair
6 representation of how you received it?

7 A. Actually the 52-D is involved -- there were three samples
8 that we split out to separate because of different batch
9 numbers. We analyzed them separately.

10 Q. Okay.

11 A. So for the reports 2730, 31 and 32, I believe we received
12 them collectively and then analyzed them because of the
13 different batch numbers to get a representative sample so --

14 Q. I guess my question to you, sir, I apologize, it was not
15 artfully phrased. When you receive the samples for analysis,
16 the blister packs were not in the cartons, were they?

17 A. I don't remember how they were packaged.

18 Q. Okay. So if -- when they were packaged when you received
19 them, the blister packs were not already in the cartons, then
20 certainly there may have been some mix up in the packaging
21 such that that batch number from the blister pack didn't match
22 the batch number on the carton; right?

23 A. It's possible.

24 Q. All right. Do you know that printing company, Field
25 Boxmore, are they located in the United Kingdom?

1 A. I already answered I don't know.

2 Q. I'm sorry. I thought that might help to refresh your
3 recollection. With respect to the Zyprexa and the color
4 differences, do you have -- where did I put your report -- you
5 talked about the color differences between the sample versus
6 the authentic. Does -- do you know whether the color of
7 Zyprexa is the same in every international market that it is
8 distributed.

9 A. Every one that I'm aware of.

10 Q. Every one that you're aware of, that color stays the
11 same, that color does not change?

12 A. It is possible for the color to change if subjected to
13 the right environmental conditions. That's one of the reasons
14 why Lilly packages it the way we do in the foil container to
15 prevent that from happening.

16 Q. Right. Okay. Thank you, sir. With respect to 52-B, do
17 you have the report here you can look at?

18 A. Right here.

19 Q. All right. On 52-B, you did the analysis of the
20 10-milligram Zyprexa. And I believe you testified it was
21 within the accepted value with respect to impurities, it met
22 the standards?

23 A. Correct.

24 Q. It met the U.S. standards?

25 A. Correct.

1 Q. But you just noticed some impurities there that were not
2 inherent with Eli Lilly products?

3 A. Correct.

4 Q. But the impurities themselves were within specification;
5 correct?

6 A. The collective quantitative value of the impurities was
7 within the percentage specification, yes.

8 Q. Okay. Thank you. The same is true with respect to
9 Exhibit No. 52-C?

10 A. 52-C is Sample 2730. I have the report here. That is
11 correct, it does meet the specifications, quantitative
12 specifications.

13 Q. All right. Now, you talked about storage. Is it
14 important to keep these stored -- and I guess the best
15 reference is what we agreed on -- all of our medications
16 stored at room temperature or cool places or something like
17 that, are there any specific storing conditions that are
18 peculiar to Zyprexa that you should observe to avoid
19 degradation of the product?

20 A. I'm not a product expert. I believe most of that
21 information is contained within the package insert that's
22 provided with the product.

23 Q. Do you have any package inserts?

24 A. Only the counterfeit ones.

25 Q. Do you have package inserts that were provided to you for

1 analysis -- I mean for inspection?

2 A. Yes, the counterfeit package inserts.

3 Q. You did look at some inserts then?

4 A. Yes.

5 Q. The samples that were submitted to you they were inserts
6 as well as -- because I didn't see any up here.

7 THE COURT: Haven't we covered all this? What's the
8 relevance of all this?

9 MR. AMANN: I was just going to get to the storing,
10 if the product had not been stored adequately.

11 THE COURT: How would that affect the quality of the
12 drug itself?

13 MR. AMANN: It might. My question -- my followup
14 questions --

15 THE COURT: Well, let's find out that.

16 Would storage affect the active ingredient level in
17 the drug?

18 THE WITNESS: Yes, it would.

19 THE COURT: How would that work?

20 THE WITNESS: It would decrease the potency. But
21 Lilly has done stress degradation studies where the product's
22 been stored at various environmental conditions to keep light,
23 moisture and we're well aware of how our product behaves under
24 those conditions. And that is the basis for our conclusion is
25 that these impurities we're observing aren't indicative of

1 anything we're familiar with seeing in our marketed product
2 now or any stress degradation studies we've done in the past.

3 THE COURT: Ask your next question.

4 MR. AMANN: Just a followup on your one question, if
5 I may, Your Honor.

6 THE COURT: All right.

7 BY MR. AMANN:

8 Q. Would the degradation studies also take into account
9 color, how the color of the product was affected?

10 A. I don't know.

11 MR. AMANN: All right. I pass the witness, Your
12 Honor.

13 THE COURT: Anything else, Mr. Louis?

14 MR. LOUIS: Yes, just one question.

15 REDIRECT EXAMINATION

16 BY MR. LOUIS:

17 Q. Mr. Amann asked you about Lilly batch numbers. Is that a
18 number -- what is the purpose of batch numbering?

19 A. Batch numbers are a unique identifier giving -- given to
20 each batch of Lilly products that goes out into the market so
21 that it can be tracked and distributed and know which market
22 the batch is going to go to. It also -- it's sort of a
23 license plate to indicate when the product was manufactured,
24 when it would expire and for traceability reason to know if
25 there's any issue with a particular batch after it gets into a

1 patient's hands.

2 Q. That's unique to Lilly?

3 A. No. Every pharmaceutical company, to my knowledge,
4 applies batch numbers to every --

5 Q. A particular batch number that's assigned to Lilly would
6 be unique to Lilly, would that be accurate?

7 A. I don't know how other companies assign their batch
8 numbering system.

9 Q. Okay. Well, let's talk about -- the batch numbers that's
10 on these drugs, would you expect some other individual to have
11 the batch number that's assigned in use that's on part of --
12 all the exhibits we've talked about?

13 A. No.

14 MR. LOUIS: No further questions.

15 MR. AMANN: Just one quick one, Your Honor, I forgot
16 to ask.

17 RECROSS-EXAMINATION

18 BY MR. AMANN:

19 Q. In a given batch number, how many pills are produced that
20 have that batch number on it?

21 A. It can vary. There are smaller batches up to very large
22 batches. It's not -- I wouldn't say it's a consistent number.
23 Every batch is "X" number of tablets or packages.

24 Q. Did you check this batch number to see how many pills
25 containing this particular batch number were out there?

1 A. I did not.

2 Q. Cold you give us an estimate on an average batch drug?

3 A. I don't know that information.

4 Q. Would it be in the millions?

5 A. I don't know. I'm not in manufacturing. I don't know.

6 MR. AMANN: Thank you, Your Honor. Pass the witness.

7 THE COURT: May the witness be excused?

8 MR. LOUIS: Yes, Your Honor.

9 MR. AMANN: Yes, Your Honor.

10 THE COURT: Thank you. You're excused, Mr. Dalton.

11 The Government may call its next witness.

12 MR. LOUIS: The Government calls JaCinta Batson to

13 the stand.

14 THE COURT: I need an amended exhibit list for those

15 52 exhibits.

16 MR. LOUIS: Yes, Your Honor.

17 THE COURT: Please come around, ma'am, and be sworn

18 as a witness.

19 Can you move all those other exhibits away from where

20 the witness is.

21 MR. LOUIS: Yes, Your Honor.

22 JaCINTA BATSON

23 having been first duly sworn, testified as follows:

24 THE COURT: Please be seated.

25 You may proceed, Mr. Louis.

1 MR. LOUIS: Thank you.

2 DIRECT EXAMINATION

3 BY MR. LOUIS:

4 Q. Place state your name and spell your last name for the
5 benefit of the ladies and gentlemen of the jury and the court
6 reporter.

7 A. JaCinta Batson, B, as in boy, a-t-s-o-n.

8 Q. And Miss Batson, how are you employed?

9 A. I'm employed with the United States Food and Drug
10 Administration Forensic Chemistry Center.

11 Q. And where is that located?

12 A. Cincinnati, Ohio.

13 Q. How long have you been employed with the Forensic
14 Chemistry Center?

15 A. Over six years.

16 Q. What is your title there?

17 A. I'm a forensic chemist.

18 Q. How long have you been employed as a forensic chemist?

19 A. About six years.

20 Q. Briefly tell the ladies and gentlemen of the jury your
21 educational background.

22 A. I have a bachelor's of science and chemistry from Wright
23 State University. I also have a Master's of science and
24 chemistry from Wright State University.

25 Q. And was employment at the FCC your first job out of, I

1 guess, master's -- after getting your master's degree?

2 A. No.

3 Q. Where else did you work?

4 A. I was also employed with the Brim Laboratory as
5 analytical chemist there.

6 Q. What is the Brim Laboratory?

7 A. The Brim Laboratory works with the EPA for sample
8 preparation. We do a lot of -- we did a lot of analysis for
9 samples that were in violation for the EPA.

10 Q. All right. So total, how many years of experience do you
11 have as a forensic chemist?

12 A. About ten years.

13 Q. All right. And does the Forensic Chemistry Center on a
14 regular basis receive samples for analysis?

15 A. Yes.

16 Q. And in reference to this case, did the Forensic Chemistry
17 Center receive several samples for analysis?

18 A. Yes.

19 Q. And did you have some connection in reference to those
20 analysis?

21 A. Yes.

22 Q. I'll try to start with Government's Exhibit -- let's
23 first look at Government's Exhibit 52-A and ask you to take a
24 look at this exhibit.

25 A. Okay.

1 Q. And what is that exhibit?

2 A. This is -- this is the remainder of the sample that -- of
3 one of the samples that we received by the FCC.

4 Q. All right. Did you do a report with respect to your
5 analysis of that sample?

6 A. Yes.

7 Q. Is this the report that you prepared?

8 A. Yes.

9 MR. LOUIS: All right. At this time I move for the
10 admission of Government's Exhibit 56 -- or pardon me.

11 BY MR. LOUIS:

12 Q. Are your initials also on the bag here?

13 A. Yes.

14 MR. LOUIS: All right. At this time I move for the
15 admission of Government's Exhibit 56-A.

16 THE COURT: 56-A?

17 MR. LOUIS: Yes.

18 THE COURT: I don't have that on my list either.

19 MR. LOUIS: I'll revise the list after lunch.

20 MR. AMANN: I have no objection.

21 THE COURT: It's admitted.

22 BY MR. LOUIS:

23 Q. All right. Is There a particular procedure that's
24 utilized once a sample is submitted for analysis?

25 A. Yes.

1 Q. What is that procedure?

2 A. Once a sample is submitted to our laboratory, our sample
3 custodian receives the sample and they log it into the system
4 at our facility. That sample is kept under lock and key until
5 it's ready for analysis.

6 Q. Now, what's the date on your report there?

7 A. The date I submitted the report?

8 Q. Yes, what's the date on your report that you submitted?

9 A. June 8th, 2007.

10 Q. Now, is that the date that an analysis was first
11 performed or done?

12 A. No.

13 Q. And do you typically do an initial analysis?

14 A. Yes.

15 Q. Was that done in this case?

16 A. Yes.

17 Q. All right. Now, what's your reference sample, the number
18 that you assigned to this particular sample that was submitted
19 for analysis?

20 A. The sample number is 405479.

21 Q. Say it one more time.

22 A. 405479.

23 Q. And also there is another number what is noted with "CIE"
24 I believe; is that right?

25 A. Yes, sir.

1 Q. And what is that number?

2 A. That number is 132863.

3 Q. And what is the significance of that last number?

4 A. The last number is the number that is assigned by the OCI
5 portion. And then we get it and we have to assign another
6 number for us in house.

7 Q. OCI, does that stand for Office of Criminal
8 Investigation?

9 A. Yes.

10 Q. Some agency submitted it for analysis?

11 A. Yes.

12 Q. And looking at -- could you open it up just briefly so we
13 can see what's inside?

14 A. We need scissors or something to open it.

15 Q. Okay. Let me see if I can help you.

16 Now, within the bag that I just tore was another bag;
17 is that right?

18 A. Yes.

19 Q. And what bag is that?

20 A. This is the bag that we received from OCI.

21 Q. All right. Now, what is it -- what is Government's
22 Exhibit No. 56-A? What was submitted for analysis?

23 A. We received one blister pack that was labeled, in part,
24 Zyprexa 10 milligrams.

25 Q. So once you received the blister pack, what's the very

1 first thing that you did to conduct an analysis to determine
2 whether it's authentic or counterfeit?

3 A. The very first thing we do is, once we receive the
4 sample, we have to log the information, the actual seal on
5 this sample. We also have to record the date we received it,
6 the title of the seal and we also have to -- there's also a
7 case name that's associated with it -- with each sample.

8 Q. All right. Now, this is a sample of Zyprexa; is that
9 right?

10 A. Yes.

11 Q. Did you have to obtain a reference sample, authentic
12 known sample of Zyprexa to conduct the analysis?

13 A. Yes, but we already had authenticals in house.

14 Q. Now, what's the first thing you do to make the comparison
15 between the authentic reference sample and then suspect sample
16 that you receive.

17 A. The first thing we do is we do a visual observation where
18 we just visually compare the suspect sample to the known
19 authentic sample.

20 Q. And so you did that in this case?

21 A. Yes.

22 Q. And what did you find?

23 A. We found that visually that the two samples were
24 consistent with each other.

25 Q. After looking at the -- inspecting it visually, what's

1 the next thing you do?

2 A. The next thing that we did was we weighed the sample. We
3 weigh individual tablets of the sample and we took the average
4 of the suspect sample and we compared it to the average of the
5 known authentic sample.

6 Q. All right. Was that consistent or inconsistent?

7 A. That was not consistent.

8 Q. And not to go into too much detail, does weighing it give
9 you any indication as to whether the components of it are
10 authentic or not?

11 A. Yes.

12 Q. Explain that for us.

13 A. Well, for most -- well, all drug companies, they have
14 specific ranges that they use for weights and other analysis.
15 And the weight of these samples were completely off from the
16 known authentic.

17 Q. And just for the record, what was the weight of this
18 sample?

19 A. I don't have it in front of me.

20 Q. All right. Now, after doing the weight comparison, what
21 type of chemical test did you do?

22 A. We did Fourier transform infrared spectroscopy or FTIR
23 spectroscopy.

24 Q. Spell that for the court reporter, please.

25 A. Okay. F-o-u-r-i-e-r, transform, t-r-a-n-s-f-o-r-m,

1 infrared, i-n-f-r-a-r-e-d, and spectroscopy, s-p -- oh, that's
2 okay? Okay.

3 Q. But the first word, Fourier, but it's FTIR, is that the
4 acronym for that?

5 A. Yes, yes.

6 Q. What's the purpose of that test?

7 A. The purpose of that test, we -- it's analytical technique
8 used in forensic science to identify chemicals and also to
9 differentiate between products.

10 Q. All right. And performing this test on Government's
11 Exhibit 56-A, Zyprexa -- is that 10 milligrams?

12 A. Yes.

13 Q. What was the result of that test?

14 A. The result of the test was that the coatings and cores
15 were not consistent with authentic Zyprexa 10-milligram tablet
16 coatings and cores.

17 Q. Do you do an examination, chemical examination of the
18 coating, which is outside?

19 A. Yes.

20 Q. And was that consistent or not?

21 A. No.

22 Q. And what specific, if you can tell us, what was the
23 difference?

24 A. I'm not sure. I don't have my report in front of me.

25 Q. All right. What do you have there?

1 A. This?

2 Q. Is that your report?

3 A. This is my lab worksheet.

4 Q. Now, with respect to the core, the core is the active
5 ingredient and filler; would that be correct?

6 A. Yes.

7 Q. And when you did the test of the active ingredient -- can
8 you tell us, what is the active ingredient for Zyprexa?

9 A. The active ingredient for Zyprexa is olanzapine.

10 Q. All right. You did the testing. What was the result of
11 the test?

12 A. The initial test by FTIR we could not determine that the
13 active ingredient was present. Additional tests needed to be
14 performed to determine the presence of olanzapine.

15 Q. Did that happen?

16 A. Yes.

17 Q. Is that part of the report that you have there?

18 A. Yes, part of the report.

19 Q. And what was the result of that?

20 A. The result showed that olanzapine was present in the
21 suspect sample.

22 Q. Do you know the amount?

23 A. Yes. The amount was equivalent to 68 percent of the
24 declared 10 milligrams per tablet of olanzapine concentration.

25 Q. Do you know whether or not that is within acceptable

1 tolerance for an authentic Zyprexa or not?

2 A. I know that it's not, but I don't have my worksheet.

3 Q. All right. Now, within Government's Exhibit 56-A -- just
4 so the jury can see -- are, to do this quickly, series of --
5 forgot the term I was going to use. But, what are these?

6 What do you call these?

7 A. Petri dishes.

8 Q. Petri dishes. Thank you. Then you have markings here;
9 is that right?

10 A. Yes.

11 Q. So you took portions of the pill and then you conducted
12 the analysis; is that right?

13 A. Yes.

14 Q. And you have several ones.

15 A. Uh-huh.

16 Q. And so we can actually see -- let me try to look at this
17 one right here. Is this the authentic sample?

18 A. No, that's the suspect sample.

19 Q. How do you know that's the suspect sample?

20 A. It has the sample number associated with it.

21 Q. All right. Then what about this one?

22 A. That is also a suspect sample.

23 Q. Okay. So you would do a review of all the suspect
24 samples?

25 A. Yes. We only use -- we want to keep some tablets intact

1 just in case further analysis is requested by another
2 laboratory.

3 Q. All right. And then you also have a vial?

4 A. Yes.

5 Q. What is in the vial?

6 A. In the vial is the remainder of the sample that was not
7 used in the analysis.

8 Q. All right. Lastly, there is a number on this plastic
9 bag. What is that number?

10 A. That is our in-house fax number.

11 Q. Why is your in-house fax number on the sample?

12 A. Again, once the sample custodian receives it, they have
13 to assign a number so we need to know what the sample number
14 is going to be for them to log it in.

15 Q. Now, let me show you another sample. I hand you what's
16 marked as Government's Exhibit 56-B and ask you is this
17 another sample that was submitted for analysis?

18 A. Yes.

19 Q. How do you know that?

20 A. Because it has our fax sample number on it.

21 Q. And do you have your signature, initials anywhere on the
22 sample?

23 A. Yes.

24 Q. Where is that?

25 A. It's on the bag and also on the seal.

1 MR. LOUIS: All right. At this time I move for
2 admission of Government's Exhibit 56-B.

3 MR. AMANN: I have no objection, Your Honor.

4 THE COURT: All right. 56-B is admitted.

5 BY MR. LOUIS:

6 Q. Looking at Government's Exhibit 56-B, what was the
7 particular pharmaceutical product that was submitted for
8 analysis?

9 A. Plavix.

10 Q. All right. Can you tell us, what is the number that was
11 assigned -- that you assigned to this exhibit?

12 A. The number we assigned was 412489.

13 Q. Then what is the number that was assigned by the Office
14 of Criminal Investigation who submitted it to you for
15 analysis?

16 A. 132868.

17 Q. All right. So this is Plavix; is that correct?

18 A. Yes.

19 Q. Any other pharmaceutical products in the sample?

20 A. No, just Plavix.

21 Q. All right. When you do an analysis, do you also do an
22 analysis of the carton itself? Do you have any reference
23 samples for that?

24 A. We do, but we didn't do it in this analysis.

25 Q. Okay. And looking at the actual pill itself, did you do

1 the same FTIR test?

2 A. Yes.

3 Q. And did you do the core and coatings?

4 A. Yes.

5 Q. What was the result of the examination -- chemical
6 examination of this sample?

7 A. The FTIR spectra, the suspect tablets coatings and cores
8 were not consistent with authentic Plavix.

9 Q. All right. Moving over here, what was the actual potency
10 of this sample?

11 A. It's not on this report.

12 Q. All right. Is There another report that might have it on
13 there?

14 A. Yes.

15 Q. Okay. It's -- what is it? What's the potency?

16 A. For authentic tablets it's supposed to be 75 milligrams
17 per tablet. For the suspect tablets I can't state what it was
18 because I don't have the report in front of me.

19 Q. All right. In the report that would have that on there,
20 is that a report that you brought with you today or not?

21 A. No, I didn't bring it with me.

22 Q. Okay. Just so we know, these are the samples that you
23 tested?

24 A. Yes.

25 Q. All right. And just so the record's clear, what were

1 your findings, authentic or not authentic?

2 A. They were not authentic.

3 Q. All right. And this is contained in the package -- is
4 that 28 milligrams or do you know?

5 A. 75 milligrams this was labeled.

6 Q. Okay. Let's now look at Government's Exhibit 56 -- let's
7 look at Government's Exhibit 56-C. Pretty big bag, is it not?

8 A. Yes.

9 Q. Looking at Government's Exhibit 56-C, is that also
10 pharmaceutical products that were submitted to the Forensic
11 Chemical Center for analysis?

12 A. Yes.

13 Q. And how do you know it was submitted?

14 A. It has our fax number on it and also has my initials and
15 my signature.

16 Q. All right. And can you tell us what date that was
17 submitted for analysis?

18 A. 05-04-2007.

19 Q. Then what is the number that was assigned to that sample
20 by your lab?

21 A. 421819.

22 Q. Then what was the number that was assigned by the Office
23 of Criminal Investigations?

24 A. 132874.

25 MR. LOUIS: All right. At this time I move for the

1 admission of Government's Exhibit No. 56-C.

2 THE COURT: What's the drug name in that sample?

3 MR. LOUIS: It's various samples in there.

4 MR. AMANN: Seems to be quite a lot here.

5 BY MR. LOUIS:

6 Q. Just for the record, can you look at the report and tell
7 the different pharmaceutical products that were submitted as
8 part of Government's Exhibit 56-C?

9 A. Yes, Tamiflu 75-milligram capsules, Zyprexa 10-milligram
10 tablets, Plavix 75-milligram tablets and Casodex 50-milligram
11 tablets.

12 Q. Okay.

13 MR. AMANN: I don't have any objection, Your Honor.

14 THE COURT: All right. 56-C is admitted.

15 This would be a good time to take our noon recess.

16 We'll stand in recess until 1:00 o'clock.

17 (There was a lunch recess taken.)

18 THE COURT: Good afternoon, ladies and gentlemen.

19 You may proceed.

20 MR. LOUIS: Thank you, Your Honor.

21 BY MR. LOUIS:

22 Q. Miss Batson, before the break, I believe I had tendered
23 to you Government's Exhibit 56-C.

24 A. Yes.

25 Q. Looking at this exhibit, does it contain multiple

1 pharmaceutical products that were submitted for analysis?

2 A. Yes.

3 Q. And I think I tore this a little bit -- are there eight
4 items that comprise this exhibit?

5 A. Yes.

6 Q. Okay. Now, you've got quite a bit up there so let's take
7 one of them, one on the top.

8 A. Okay.

9 Q. Tell us what the pharmaceutical product was that was
10 submitted?

11 A. Zyprexa and Tamiflu.

12 Q. Okay. So you got Zyprexa and Tamiflu in that one bag
13 there?

14 A. Yes.

15 Q. You have a number also on that; is that right?

16 A. Yes.

17 Q. You call it a fax number?

18 A. Yes.

19 Q. What's the fax number on there?

20 A. 421819.

21 Q. Okay. Is that going to be the same number that's
22 consistent with all the items that were submitted for analysis
23 with this Exhibit 56-C?

24 A. Yes.

25 Q. Now, in looking at those samples -- let's take out one

1 first -- and could you give us the date that that was
2 submitted to the lab for analysis?

3 A. Submitted 05-04-2007.

4 Q. All right. And did you do an analysis, the FTIR test, on
5 this sample as well?

6 A. Yes.

7 Q. And is that the core and coatings that you talked about
8 earlier?

9 A. For the Tamiflu, since they're capsules, only the capsule
10 contents.

11 Q. So what you have that you pulled out, is that Zyprexa or
12 Tamiflu?

13 A. This one is Tamiflu.

14 Q. Okay. All right. So for the Tamiflu, how many capsules
15 did you review for the -- to do the chemical analysis?

16 A. Two.

17 Q. How many is left in that blister foil there?

18 A. This is just empty.

19 Q. Okay. And are they in the Petri dishes?

20 A. Yes.

21 Q. All right. And in conducting the analysis of the
22 contents of the Tamiflu capsules, what was the result of the
23 FTIR test?

24 A. The FTIR spectra, the suspect capsule contents were not
25 consistent with authentic Tamiflu 75-milligram capsule

1 contents.

2 Q. Were you able to determine what the actual percentage of
3 the -- first of all, what's the active ingredient in the
4 Tamiflu?

5 A. Oseltamivir phosphate.

6 Q. Oseltamivir phosphate?

7 A. Uh-huh.

8 Q. What was the amount of the active ingredient that was
9 found in the sample that was submitted for analysis?

10 A. The amount of active ingredient was 53.0 milligrams per
11 capsule which is equivalent to 71 percent of the declared
12 75 milligrams per capsule.

13 Q. All right. Now, looking at the Zyprexa that you have
14 there, did you also do the FTIR test for that?

15 A. Yes.

16 Q. And what was the active ingredient for that?

17 A. Olanzapine.

18 Q. And what was the percentage of olanzapine in the sample
19 that you performed an analysis of?

20 A. For one of the tablets the percentage was 69 percent. An
21 additional tablet was analyzed and that one had 72 percent of
22 olanzapine.

23 Q. So you received a -- was that a seven-tablet blister
24 strip?

25 A. Yes.

1 Q. And how many tablets were actually analyzed?

2 A. I believe six. Yes.

3 Q. And of the two that you have the results for, what was
4 that again?

5 A. Two of them were used for FTIR and then additional two
6 were used for a concentration. And the percentage for one of
7 them was 69 percent and the other one was 72 percent.

8 Q. Okay. So you did separate tests on separate samples; is
9 that right?

10 A. Yes.

11 Q. Okay. And in all the tests that were performed, the FTIR
12 test, was that consistent with authentic Zyprexa?

13 A. No.

14 Q. All right. And then the testing that you did to
15 determine the amount of the active ingredient, was that
16 consistent with the amount that's declared -- is that 75
17 milligrams?

18 A. Yes.

19 Q. What was present?

20 A. For which -- excuse me, for which one again, for the
21 Tamiflu or the Zyprexa?

22 Q. Zyprexa.

23 A. Zyprexa is 10 milligrams.

24 Q. 10 milligrams?

25 A. Yes. And for one of the tablets it was 6.9 milligrams

1 per tablet. And that was the one that was 69 percent. The
2 other tablet was 7.2 milligrams per tablet. And that was
3 72 percent equivalent of the 10 milligrams.

4 Q. All right. So we don't get confused, put those back in
5 its packaging.

6 A. Okay.

7 Q. Now, on your report does it indicate what the -- I think
8 you told us what the number was for the Office of Criminal
9 Investigation, what number they assigned to that. What number
10 is that again?

11 A. That number is 132874.

12 Q. Okay. Now, let me pull that aside. Would you take a
13 look at the next sample that is part of Government's
14 Exhibit 56-C. And what pharmaceutical drug was submitted for
15 analysis in this sample?

16 A. Tamiflu.

17 Q. And again, is this 75 milligrams?

18 A. Yes.

19 Q. And what type of test was done on this sample?

20 A. The same test, FTIR spectroscopy.

21 Q. And how many capsules on the blister pack?

22 A. This originally contained ten.

23 Q. And did you take all of them out and put them in the
24 Petri dishes?

25 A. Yes.

1 Q. How many were analyzed?

2 A. Five.

3 Q. And what was the result of the analysis with respect
4 to -- we won't go into all five of them, but did any of them
5 have the amount of the active ingredient that would add up to
6 75 milligrams? I guess for the record you need to tell us
7 what they are.

8 A. Okay. The Tamiflu -- for this item, the Tamiflu was 53.0
9 milligrams per capsule, which is equivalent to 71 percent of
10 the declared 75 milligrams per capsule.

11 Q. Is that the only pharmaceutical product that was in that
12 package?

13 A. Yes.

14 Q. Okay. There's some writing on there. Is that writing --
15 whose name is on that bag?

16 A. The name on this bag is Doug Mason.

17 Q. Did you write that or is that how it was received?

18 A. This is how it was received.

19 Q. Let me take that sample from you. And if you would look
20 at the next bag and tell us what pharmaceutical product was
21 submitted for analysis?

22 A. Plavix and Zyprexa.

23 Q. And let's talk about the Plavix first.

24 A. Okay.

25 Q. Is that the seven count or how many tablets in this

1 Plavix?

2 A. 28.

3 Q. How many of the pills were analyzed?

4 A. I believe, nine.

5 Q. All right. And what was -- you did a FTIR test again?

6 A. Yes.

7 Q. And what was the result of that test on the Plavix pills?

8 A. The tablets coatings and cores were not consistent with
9 authentic Plavix.

10 Q. In addition, did you determine what the amount of the
11 active ingredient was in the samples that were analyzed?

12 A. Yes.

13 Q. What was that?

14 A. 53.7 percent.

15 Q. Of the declared amount?

16 A. Yes.

17 Q. So it did not have the amount of the active ingredient?

18 A. Correct.

19 Q. You also analyzed Zyprexa?

20 A. Yes.

21 Q. After doing the test on Zyprexa, what was the result of
22 the coatings and cores test -- or test on the coatings and
23 cores?

24 A. The coatings and cores were not consistent with authentic
25 Zyprexa.

1 Q. What was the amount of the active ingredient present when
2 the test was done?

3 A. The amount is 72 percent of the declared 10-milligram
4 tablets.

5 Q. And then you have something in a vial. What is this?

6 A. This is the remainder of sampling that was not used.

7 Q. All right. Let's put those back. Let's move to the next
8 part of Government's Exhibit 56-C. Does that also have the
9 name Doug Mason on the bag that was submitted for analysis?

10 A. Yes.

11 Q. Looking at that portion sample, what was being
12 analyzed -- or what was analyzed?

13 A. Plavix, Zyprexa and Casodex.

14 Q. Okay. For the Plavix, did you do -- now, do you ever do
15 an analysis of the packaging yourself? I mean, does the FCC
16 do analysis of the packaging?

17 A. Yes, we do. In this case we did not.

18 Q. All right. In looking at the Plavix, did you do the FTIR
19 test?

20 A. Yes.

21 Q. Was that consistent or inconsistent with authentic
22 Plavix?

23 A. It was not consistent.

24 Q. And what's the milligrams, for the record?

25 A. 75 milligrams.

1 Q. And then the amount of the active ingredient in the
2 sample that was tested?

3 A. 52.1 percent of the declared 75 milligrams.

4 Q. All right. And then let's move next to the Zyprexa.

5 A. Okay.

6 Q. Were the coatings and cores consistent with authentic
7 Zyprexa?

8 A. No, they were not consistent.

9 Q. Then what was the amount of the active ingredient
10 present?

11 A. 69 percent of declared 10 milligrams per tablet.

12 Q. 69 percent of the -- so that was subpotent -- it would be
13 subpotent then?

14 A. Yes.

15 Q. Then looking at the Casodex, was the coatings and cores
16 consistent or inconsistent with authentic Casodex?

17 A. The coatings and cores were not consistent.

18 Q. What is the active ingredient in Casodex?

19 A. Bicalutamide.

20 Q. Okay. Then what was the amount of the active ingredient
21 of that API?

22 A. That ingredient wasn't recorded on this report.

23 Q. Okay. Let's move to the next one. Do you have another
24 report that has this one?

25 A. No.

1 Q. Is that all of --

2 A. Yes.

3 Q. Now, within that were all these bags; is that right?

4 A. Yes.

5 Q. All right. Let's move to the next exhibit, Government's
6 Exhibit 56. Looking at this exhibit, was it also submitted to
7 the FCC, Forensic Chemical Center for analysis?

8 A. Yes.

9 Q. And what was the date that it was submitted?

10 A. It was submitted December 27, 2006.

11 Q. What product was submitted?

12 A. Tamiflu.

13 Q. Is your initial on that sample?

14 A. Yes.

15 MR. LOUIS: At this time I move for the admission of
16 Government's Exhibit 56.

17 THE COURT: 56 is Tamiflu only?

18 MR. LOUIS: Tamiflu only.

19 MR. AMANN: No objection, Your Honor.

20 THE COURT: Government's Exhibit 56 is admitted.

21 BY MR. LOUIS:

22 Q. And the Tamiflu, that is in capsule form; is that right?

23 A. Yes.

24 Q. Is that 75 milligrams?

25 A. Yes.

1 Q. And did you do an analysis of the powder of the Tamiflu
2 capsule?

3 A. Yes.

4 Q. And what was the amount of the active ingredient that was
5 present?

6 A. 71 percent of the declared 75 milligrams per capsule.

7 Q. How many capsules were analyzed?

8 A. Seven.

9 Q. And was it part of a blister strip, is that what you
10 received?

11 A. Yes.

12 Q. And how many are contained in the blister strip?

13 A. Ten.

14 Q. Now, let me show you what's marked as Government's
15 Exhibit No. 56-D.

16 THE COURT: 56-B, as in boy?

17 MR. LOUIS: 56-D as in David.

18 BY MR. LOUIS:

19 Q. And, again, is that a sample that was submitted to the
20 Forensic Chemistry Center for analysis?

21 A. Yes.

22 Q. What's the date that that was submitted for analysis?

23 A. June 18th, 2007.

24 Q. And did you conduct an analysis of this exhibit?

25 A. Yes.

1 Q. Are your initials on the exhibit?

2 A. Yes.

3 Q. At this time I move for the admission of Government's
4 Exhibit 56-D.

5 MR. AMANN: I have no objection, Your Honor. I guess
6 56-D is Aricept and Plavix.

7 THE COURT: All right. It's admitted.

8 BY MR. LOUIS:

9 Q. Looking at Government's Exhibit 56-D, was it also
10 submitted in an evidence envelope submitted by Doug Mason?

11 A. Yes.

12 Q. All right. Government's Exhibit 56-D, what were the
13 pharmaceutical products that were submitted for analysis?

14 A. Aricept, Plavix and Tamiflu.

15 Q. Looking first at the Aricept, did you receive it in the
16 packaging?

17 A. Yes.

18 Q. And is it blister strips?

19 A. Yes.

20 Q. How many blister strips did you receive.

21 A. Two.

22 Q. And how many count -- how many pills in the blister
23 strips?

24 A. 14.

25 Q. Then what was the milligrams that's supposed to be per

1 each tablet?

2 A. 10 milligrams.

3 Q. And during the FTIR analysis, was it consistent or
4 inconsistent with authentic Aricept?

5 A. It was not consistent.

6 Q. And what is the active ingredient in Aricept?

7 A. Donepezil.

8 Q. Say that one more time.

9 A. Donepezil.

10 Q. How do you spell that?

11 A. D-o-n-e-p-e-z-i-l.

12 Q. All right. Thanks. What was the amount of the active
13 ingredient that was found when the test was performed?

14 A. It was 8.15 milligrams per tablet.

15 Q. Does that mean it was subpotent?

16 A. Yes.

17 Q. And then did you do also an analysis of the Plavix that
18 you received?

19 A. Yes.

20 Q. Same test, FTIR test?

21 A. Uh-huh.

22 Q. And how many pills of the Plavix were analyzed?

23 A. Six.

24 Q. And of the six that were analyzed, what was the result of
25 doing the FTIR test?

1 A. The tablet coatings and cores were not consistent with
2 authentic Plavix 75-milligram tablets.

3 Q. And did you do a test for the active ingredient?

4 A. Yes.

5 Q. And what was the percent of the active ingredient found
6 when that sample was tested?

7 A. 62 percent of the declared 75 milligrams per tablet.

8 Q. And then, lastly, you have there Aricept, Plavix and what
9 else?

10 A. Tamiflu.

11 Q. Tamiflu. Of the 75 milligrams of Tamiflu, the active
12 ingredient of Tamiflu, what was determined when you did a test
13 on the sample?

14 A. 69 percent of the declared 75 milligrams per capsule.

15 Q. Of all the samples that we have gone over, Government's
16 Exhibit 56, 56-A, B and C, I believe D, did you find any of
17 the samples to be consistent with the authentic pharmaceutical
18 product?

19 A. No.

20 MR. LOUIS: At this time I pass the witness.

21 MR. AMANN: May I, Your Honor?

22 THE COURT: Yes, you may proceed to cross-examine the
23 witness.

24 MR. AMANN: Thank you.

25

1 CROSS-EXAMINATION

2 BY MR. AMANN:

3 Q. Is it Miss Batson?

4 A. Yes.

5 Q. Miss Batson, good afternoon. My name is Colin Amann.

6 A. Good afternoon.

7 Q. You have been a forensic chemist for six years. Let's
8 talk about -- let's try to work -- since we've got them in a
9 pile up here, they're probably in reverse order. I just want
10 to ask you a few questions.

11 With respect to Government's 56-D, did you at any
12 time -- I'm pulling out the cartons for Plavix and the cartons
13 for Aricept -- did you at any time do a visual inspection
14 with -- between these cartons and what you knew to be real
15 cartons?

16 A. No. Our main focus was specifically on the product.

17 Q. All right. These boxes, the language there, if you know,
18 does it appear to be French?

19 A. Yes.

20 Q. All right. With respect to the pills, did you analyze
21 these pills, the Tamiflu, the Aricept, did you do a visual
22 inspection -- let's say, for example, the Tamiflu that was
23 submitted to you and what you knew to be real Tamiflu?

24 A. Yes.

25 Q. Do you have that real Tamiflu example here with you

1 today?

2 A. No.

3 Q. Do you have the real Aricept sample?

4 A. No.

5 Q. All right. And let's just speed things up. With respect
6 to all of the Government's exhibits that were submitted to you
7 for analysis, do you have here with you today the actual
8 reference samples that you used?

9 A. No.

10 Q. But you did perform a visual inspection, did you say?

11 A. Yes.

12 Q. All right. And that -- you don't have any reference for
13 any of the Government's exhibits that we talked about or that,
14 I believe, are 56-B, C, and -- I think that's it.

15 A. For the authenticics?

16 Q. Yes. You don't have the authenticics here?

17 A. No.

18 Q. All right. Now, you are a chemist; right?

19 A. Yes.

20 Q. Are you familiar with the chemical composition of
21 Tamiflu?

22 A. Somewhat.

23 Q. Do you know what's in it?

24 A. Yes.

25 Q. Do you have any idea how it's made?

1 A. No.

2 Q. Do you know -- did you say the major component was
3 oseltamivir --

4 A. Yes.

5 Q. -- right?

6 Am I saying that even close?

7 A. You're close.

8 Q. Okay. I'm going to show you just for demonstrative
9 purposes to see if you understand it, it's not an exhibit per
10 se. Do you recognize any of those chemicals listed on that
11 sheet?

12 A. I recognize a couple of them. But in reference to
13 Tamiflu, no, I'm not sure.

14 Q. You're not sure?

15 A. Yes.

16 Q. Does this appear to you to be the process that is
17 necessary to actually make the drug?

18 A. I'm not sure.

19 Q. Not sure?

20 A. Yes.

21 Q. Okay. Fair enough. Do you know where or do you know
22 if -- let's take Tamiflu again for example. Who is the
23 manufacturer for Tamiflu?

24 A. Roche.

25 Q. Roche. Do you know if Roche has a manufacturing facility

1 across the world?

2 A. I'm not sure.

3 Q. Do you know where -- do you know why the drug Tamiflu was
4 developed?

5 A. Yes.

6 Q. Why was that?

7 A. Because of bird flu.

8 Q. Bird flu originated where, if you know?

9 A. I'm not sure.

10 Q. Not sure. Now, with respect to Government's
11 Exhibit 56-C -- I think that's the one that had a bunch of
12 things in one bag. Let's see if you can find the Casodex out
13 of here for me.

14 A. This one isn't the right sample.

15 Q. Let me grab another one of these. Maybe this is it. Is
16 that the one that has the Casodex?

17 A. Yes.

18 Q. Pull that out for me, please.

19 All right. You -- and this is the only -- well,
20 there was Casodex in there and there was also Plavix as well;
21 right?

22 A. Yes.

23 Q. And when you were doing the separate samples and
24 analyzing them, you kept them separate by the individual
25 numbers that you have on your Petri dishes?

1 A. Yes.

2 Q. So you knew what was what?

3 A. Uh-huh.

4 Q. The Casodex again appears to be in French?

5 A. Yes.

6 Q. Now, I believe in your report -- do you know what -- when
7 I say "API," do you know what that is?

8 A. Yes.

9 Q. What does that mean?

10 A. Active pharmaceutical ingredient.

11 Q. The active pharmaceutical ingredient. And that's what
12 you were checking for, the active pharmaceutical ingredients
13 in all of these?

14 A. Yes.

15 Q. Now, with respect to the Casodex, I'm wondering if I
16 heard you right. Did you say that you did not test for the
17 API or it just -- it was not recorded?

18 A. We did test for API. It was the amount of API that we
19 did not test for.

20 Q. The amount of API is what you're trying to determine
21 though; correct?

22 A. No.

23 Q. All right. Do you know what the API is for Casodex?

24 And while you're looking for that, let me ask you an
25 intermediate question. When you are -- you have published

1 values for all of these APIs somewhere or do you actually take
2 what you know to be a genuine pill and analyze it at the same
3 time that you're analyzing the sample?

4 A. No. We actually contact the pharmaceutical companies and
5 they send us authentic samples. For the FTIR analysis, we
6 analyze them previously and we add them to our library. So
7 once we do a suspect comparison, it's based off of what we
8 have in our library. So it's not a direct comparison, just
9 one tablet next to each other.

10 Q. All right. And what was the API for Casodex? What is
11 that value?

12 A. I don't have that value, the value of it. I have the
13 name for it.

14 Q. You have the name of the drug?

15 A. Yes.

16 Q. The guts of the drug; right? What's the name of that?

17 A. Bicalutamide.

18 Q. All right. And what was the -- that's the active
19 ingredient, that's what makes Casodex work?

20 A. Yes.

21 Q. And what was the recorded value when you tested the
22 sample that was submitted to you?

23 A. The recorded value for --

24 Q. The API. How much of that, the guts of the stuff, was
25 there?

1 A. On the actual box?

2 Q. In the tablet.

3 A. Well, I'm not understanding the question.

4 Q. Okay. I'm sorry if I'm not being clear. You tested the
5 pills; right?

6 A. Uh-huh.

7 Q. And what you did is you popped one of these pills out and
8 put it into your machine and ran the machine and the machine
9 told you how much of the active ingredient was there?

10 A. No. The FTIR doesn't tell us how much Is There, it just
11 tells us that it's there.

12 Q. All right. So the FTIR --

13 A. Yes.

14 Q. -- that's a qualitative measurement and not a
15 quantitative?

16 A. Exactly.

17 Q. So it tells you what's there and doesn't tell you
18 qualitative versus how much Is There quantitative?

19 A. Correct.

20 Q. All right. So we're not trying to figure out how much,
21 you were just trying to figure out if it was there?

22 A. For this sample.

23 Q. Yes.

24 A. Yes.

25 Q. Was it there?

1 A. Yes.

2 Q. Okay. So the guts of the drug was there?

3 A. Uh-huh.

4 Q. The real chemical was present?

5 A. The chemical -- the chemical that drug active was
6 present.

7 Q. You just don't know whether it matched up to the value
8 quantitatively that it was supposed to be?

9 A. Yes.

10 Q. All right. So you just don't know?

11 A. Yes, we didn't run a test for that one.

12 Q. All right. That's Casodex.

13 MR. AMANN: May I have just a quick moment, Your
14 Honor?

15 THE COURT: Yes.

16 BY MR. AMANN:

17 Q. What, again, is the active ingredient for Tamiflu?

18 A. Oseltamivir phosphate.

19 Q. And do you know how that active ingredient is harvested
20 or obtained, from what plant, from what chemical synthesis, do
21 you have any idea?

22 A. No.

23 MR. AMANN: Pass the witness, Your Honor.

24 THE COURT: Anything else?

25 MR. LOUIS: One question.

1 REDIRECT EXAMINATION

2 BY MR. LOUIS:

3 Q. When you performed the test on the Casodex, did you do
4 the testing for the coatings and the cores?

5 A. Yes.

6 Q. And was it consistent or inconsistent with Casodex?

7 A. It was not consistent.

8 MR. LOUIS: No further questions.

9 THE COURT: May this witness be excused?

10 MR. AMANN: Yes, sir.

11 THE COURT: Thank you, ma'am, you're excused.

12 The Government may call its next witness.

13 MR. LEWIS: The United States now calls Clint Jones,
14 Your Honor.

15 MR. BUCKLEY: Your Honor, if it's all right with you,
16 I'll be taking this witness on cross.

17 THE COURT: So we're changing teams here. Okay.

18 MR. AMANN: He's on my team, Judge.

19 THE COURT: Well, we're substituting.

20 Call your next witness.

21 MR. LEWIS: Thank you, Your Honor.

22 THE COURT: Please come around, sir, and be sworn as
23 a witness. Please raise your right hand and be sworn.

24 CLINT JONES

25 having been first duly sworn, testified as follows:

1 THE COURT: Be seated.

2 Mr. Lewis, you may proceed.

3 MR. LEWIS: Thank you very much, Your Honor.

4 DIRECT EXAMINATION

5 BY MR. LEWIS:

6 Q. Mr. Jones, please state your full name and spell your
7 last name for the benefit of the members of the jury and the
8 court reporter.

9 A. My name is Alistar Clinton Jones. J-o-n-e-s is how you
10 spell my surname.

11 Q. And how are you employed, sir?

12 A. I'm currently employed by the MHRA, who are the medical
13 health care products side of regulatory agency in the UK. And
14 basically is part of the Department of Health.

15 Q. Part of the Department of Health?

16 A. Correct, sir, yes.

17 Q. And how long have you been employed by the MHRA?

18 A. Two years.

19 Q. And where did you work before you were hired by the MHRA?

20 A. Prior to that I worked with law enforcement for 27 years.
21 I was a detective with Scotland Yard. I worked on numerous
22 drug squads, national crime squad where I investigated serious
23 and organized crime internationally and nationally.

24 THE COURT: Would you pull the microphone to you,
25 please, so we can hear you a little bit better?

1 THE WITNESS: Yes, sir.

2 THE COURT: Thank you.

3 A. My final post within the police was in touch with the
4 drug squad with Customs officers in the metropolitan police
5 and Scotland Yard.

6 BY MR. LEWIS:

7 Q. Is it fair to say that you have quite a bit of law
8 enforcement experience?

9 A. I do, sir, yes.

10 Q. Did you retire from Scotland Yard?

11 A. Yes, I did, 27 years service.

12 Q. What is the your current position with the MHRA?

13 A. I'm an investigator with the MHRA.

14 Q. And what are your general responsibilities and duties as
15 an investigator?

16 A. The MHRA is governed by the Medicines Act which regulates
17 the issue of licenses, the manufacture and distribution of
18 medicines and any breaches of the manufacture, the
19 distribution or license breaches, the investigation department
20 where I work we investigate it and prosecute, if necessary.

21 Q. And what geographic region is the MHRA responsible for?
22 In other words, is the MHRA responsible for a city, for a
23 town, for a country, can you tell us what geographic region
24 the MHRA is responsible for?

25 A. It would be the UK, England, Wales, Scotland, Ireland.

1 Q. And tell us, once again, the countries that are in the
2 UK.

3 A. England, Wales, Scotland and Northern Ireland.

4 Q. And do you as an investigator for the MHRA, can you
5 travel throughout the entire UK to do your investigation as
6 necessary?

7 A. Yes, I can, sir.

8 Q. How many other investigators are employed by the MHRA?

9 A. 18 total.

10 Q. You're part of the 18, you're one of the 18?

11 A. I am, sir, yes.

12 Q. Do you know what a recall notice is as it pertains to the
13 MHRA and pharmaceutical drugs?

14 A. Yes, I do.

15 Q. Does the MHRA issue recall notices from time to time?

16 A. Yes, they do.

17 Q. What is a recall notice that is issued by the MHRA, why
18 might the MHRA issue a recall notice?

19 A. Recall notices are graded from 1 to either 3 or 4, 3 or 4
20 being the less serious, 1 being the most serious.

21 For example, if a recall notice was issued for a
22 recall of just 1, that would be an instruction to remove
23 straight away products from supply chain, from market because
24 seriousness to public health.

25 2 would be a lesser risk for public health. And on

1 occasion give people 48 hours to remove stock or quarantine
2 medicines.

3 And 3 may be a breach, maybe packaging or something
4 similar, which is obviously, nothing serious as 1, which would
5 be counterfeit medicines, remove now from the market, don't
6 supply and quarantine.

7 Q. And how is a recall notice posted by the MHRA? How does
8 an individual or how does a pharmaceutical industry learn that
9 a recall notice has been issued by the MHRA?

10 A. They're issued -- posted on the MHRA website and also
11 verbally to industry.

12 Q. In the year 2007 or prior to 2007, did there come a point
13 in time when you learned of a breach of the medical --
14 pharmaceutical supply chain, in other words, that a recall
15 notice or more than one recall notice was issued in the past
16 two years?

17 A. That's correct, sir, yes, in May 2007 was the last
18 serious recall that I'm aware of.

19 Q. Let me show you what's already been admitted into
20 evidence as Government's Exhibit No. 32 and ask you have you
21 seen these documents before. These are copies of the recall
22 notices. Let me ask you to take a look at those and ask if
23 you've seen these documents before.

24 A. Yes, I have.

25 Q. Are these recall notices that were issued by the MHRA in

1 the year 2007?

2 A. That is correct, yes. These are recalls -- this is for
3 the most serious breach. These are recall notices, basically,
4 remove from the market immediately and quarantine.

5 Q. Let's take a look at -- I'm going to publish this for the
6 benefit of the jury. This is the page -- the first page in
7 Government's Exhibit No. 32. This says "Drug Alert." Can you
8 see that, sir?

9 A. I can, yes.

10 Q. Do you see the date on this recall notice?

11 A. 24th of May.

12 Q. What drug is being recalled pursuant to this recall
13 notice dated may 24th, 2007?

14 A. This refers to the drug Zyprexa.

15 Q. And do you see the dosage amount, 10 milligrams?

16 A. 10 milligrams.

17 Q. And if you look at the first paragraph, you'll forgive my
18 highlighting, but do you see the manufacturer of the drug
19 Zyprexa that's listed here on this recall notice?

20 A. Yes, I do. It's Eli Lilly, sir.

21 Q. Eli Lilly?

22 A. That's correct.

23 Q. And do you see the lot numbers that are associated with
24 the recall?

25 A. My eyesight's not too good. I believe that says 505 at

1 the end.

2 Q. And do you see that before that recall notice -- I'm
3 sorry, that lot number, there are two other numbers.

4 A. I can't, sir, I can't read the numbers from here.

5 Q. Okay. Let me hand this to you and see if you can read
6 it.

7 A. Yes, I can.

8 Q. What are the two numbers that precede the last lot
9 number?

10 A. These are A200127, A216454.

11 Q. Let me ask you my next question. Let me show you the
12 documents, then I'll publish it to the jury. On Page 2 of
13 this recall notice, if you can read this to the members of the
14 jury, there's a paragraph that is with a title, with a heading
15 "Actions Required." And then it begins, "We regret." Can you
16 read it out loud for the members of the jury?

17 A. "We request," sir.

18 Q. Yes.

19 A. This states, "We request that all stock of the attached
20 lot number and variants be returned to Eli Lilly for
21 examination and suggest you keep full details of any returns.
22 Please telephone the Customer Services Team at Eli Lilly" and
23 there's a phone number given.

24 Q. Why would the MHRA request that a person receiving the
25 drugs that are subject to the recall return those drugs to the

1 manufacturer?

2 A. The manufacturer, obviously, would be able to establish
3 almost immediately if the drugs were counterfeit or not.

4 Q. And let me ask you another question about this particular
5 notice. On the third page near the bottom there is a question
6 in bold and I'll read the question and then I'd like you to
7 read what follows. The question in bold is: "Why have you
8 requested that all stock goes to Lilly for examination?" Can
9 you read the stated answer by MHRA?

10 A. Yes. The MHRA states: "Although there are visual
11 differences between genuine and counterfeit stock some are
12 subtle and we do not feel the recipients should be asked to do
13 this work. In addition, we need to obtain as much information
14 as possible about this problem."

15 Q. So in that paragraph is the MHRA telling the public that
16 the public or the person receiving the drug shouldn't make an
17 attempt on their own to determine whether they are authentic
18 or counterfeit and that that responsibility lies with the MHRA
19 and manufacturer; is that what that paragraph states?

20 A. That is also correct, yes.

21 Q. When you learned that there were certain drugs subject to
22 the recall, did you begin an investigation into where those
23 drugs originated, where they came from?

24 A. Yes, we did, yes.

25 Q. Did you learn during your investigation of a gentleman or

1 person by the name of Kevin Xu?

2 A. Yes, that's correct, sir.

3 Q. And what did you learn about Mr. Xu?

4 A. As a result of --

5 MR. BUCKLEY: Object to hearsay.

6 THE COURT: You're going to have to show the
7 foundation for his knowledge to be sure that it's based on
8 admissible evidence.

9 BY MR. LEWIS:

10 Q. In the course of your investigation, did you have contact
11 with officials from the United States Immigration and Customs
12 Enforcement Agency?

13 THE WITNESS: That is correct, Your Honor, yes.

14 BY MR. LEWIS:

15 Q. Did you request a copy of the images and documents on
16 Mr. Xu's computer?

17 A. We did, yes.

18 Q. And was that provided to you?

19 A. It was, sir, yes.

20 Q. Was that provided you by agents with the U.S. Customs and
21 Immigration Enforcement Agency?

22 A. Yes, it was.

23 Q. Did you review the documents and the images on Mr. Xu's
24 computer?

25 A. Yes, I did.

1 Q. In reviewing those images, did you find photographs on
2 Mr. Xu's computer of pharmaceutical drugs that were the same
3 as the pharmaceutical drugs that are listed in the recall
4 notices?

5 A. Yes, we did. On the computer it's quite clearly seen the
6 three products under our investigation was images of
7 documents -- of the products, sorry. And it also shown the
8 same lot numbers from our recall on the computer.

9 Q. So in your investigation you discovered images of Zyprexa
10 on Mr. Xu's computer?

11 A. That's correct, yes.

12 Q. And you also discovered images of Plavix?

13 A. That's correct, sir, yes.

14 Q. Plavix is another one of the pharmaceutical drugs listed
15 in the recall notice?

16 A. Yes.

17 Q. And the date of the recall notice for the Plavix is May
18 25th, 2007; is that correct?

19 A. That's correct, sir.

20 Q. And what is the lot number -- well, let me hand it to you
21 so you can see it up close. There are two lot numbers for the
22 Plavix that was recalled. Can you read to the jury the two
23 lot numbers?

24 A. The lot numbers are 3098 and 6Y098.

25 Q. Thank you. Let me next show you the recall notice for

1 Casodex. Can you see the date of this recall notice?

2 A. 1st of June, sir.

3 Q. June 1st, what year?

4 A. 2007.

5 Q. And the dosage amount of the Casodex tablets listed in
6 the recall notice, is it 50 milligrams?

7 A. Yes, sir.

8 Q. Let me hand you this recall notice and ask you the name
9 of the manufacturer as stated in the recall notice and the lot
10 number for the Casodex?

11 A. Lot number for the Casodex is 65520. And AstraZeneca is
12 the manufacturer.

13 Q. So for the three drugs that are listed in the recall
14 notices, the Casodex, Plavix and the Zyprexa, you found
15 imaging of all three of these on Mr. Xu's computer with the
16 lot numbers associated with the recall notices; is that
17 correct?

18 A. That is correct, yes.

19 Q. Are recall notices issued by the MHRA on a frequent basis
20 for counterfeit pharmaceuticals; is that a common occurrence
21 or uncommon occurrence?

22 A. It's extremely rare for the MHRA to issue such a high
23 Level 1 recall for counterfeit medicines.

24 Q. Why do you believe it is so rare?

25 A. Because the MHRA have strict regulations in the issue of

1 licenses and control of the medicines. It's a very rare
2 happening, it's very -- the opportunity for it to happen is
3 small so it becomes very rare.

4 Q. Pharmaceutical drugs are highly regulated within the UK;
5 is that correct?

6 A. Strictly and highly regulated, controlled by licenses and
7 other conditions.

8 Q. Have you heard of the term "parallel importing"?

9 A. I have, sir, yes.

10 Q. Explain to the members of the jury and to the Court what
11 parallel importing is as it's your understanding?

12 A. Within Europe products can be moved from one country to
13 another. Europe is licensed the same throughout. So, for
14 example, if a French-labeled product was in France, someone
15 from the UK, a wholesaler, licensed wholesaler, could lawfully
16 purchase the French product. The reason for doing that would
17 be that the French product would be a lot cheaper to buy in
18 France so the UK wholesale dealer, licensed, would make money
19 by buying that product. However, what he would have to do is
20 bring the product to the UK and then relabel and repackage the
21 item so it could be suitable for sale within the UK. It would
22 have French packaging and French writing on it, inside the
23 packet there's a thing called a patient information leaflet.
24 That's in French. So when the product's purchased, they'll
25 take that out in the UK and they'll put an English patient

1 information leaflet inside there. They have the option then
2 of changing the package on the outside to an English package
3 or purely put the label affixed and glued to the outside of
4 the package in English explaining the dosage and medicines,
5 directions for use, et cetera, basically imaging what the
6 French say in English.

7 Practically speak, something most licensed dealers
8 would use, the sticky label on the outside of the French
9 packaging because, obviously, it's more profitable to them.
10 There's no lawful requirement for them to throw away the
11 package, purely sticking the label on is sufficient. But that
12 would then legitimize the drug to be sold within the UK.

13 Q. Okay. You said quite a bit of information there. Let me
14 see if I can break it down and ask you a few questions. If a
15 company were to engage in parallel importing within the UK,
16 would that company have to be licensed in order to do so?

17 A. It would, sir, yes.

18 Q. And is that license issued by the MHRA?

19 A. That's correct.

20 Q. Is Mr. Kevin Xu licensed as a parallel importer with the
21 MHRA?

22 A. No, he's not.

23 Q. The company, Orient Pacific International, is that
24 company licensed with the MHRA as a parallel importer?

25 A. No, there's no license.

1 Q. If a company is engaged in parallel importing within the
2 UK and they are taking a product, a pharmaceutical product and
3 they are repackaging or relabelling the product, you say the
4 product that's being repackaged or relabeled, is that product
5 required to be authentic, in other words, non-counterfeit?

6 A. That is correct, sir, yes.

7 Q. So whether it is the original manufacturer's carton or
8 whether it is parallel importer's carton, the product itself,
9 the contents of the carton must be authentic, non-counterfeit;
10 is that correct?

11 A. That is correct, sir.

12 Q. Let me show you what's already been admitted into
13 evidence, a few exhibits. The first exhibit I will show you
14 is Government's Exhibit 37-A, which is an evidence bag
15 containing several cartons of Plavix. I will show you one
16 carton and I want to ask you a few questions. So I'll take
17 one carton out of the bag, hand it to you, show you the front
18 and the back. On the back of that carton, do you see the word
19 "France"?

20 A. Yes, I do, sir, yes.

21 Q. And does the language that appears on the carton, does
22 that language appear to be French?

23 A. Yes, that's correct.

24 Q. For the members of the jury, I'll show the front of the
25 box, 75 milligrams, and I'll show the side of the box. And,

1 again, that language appears to be French, sir?

2 A. That's correct, sir, yes.

3 Q. Are you familiar with the term, "vignette, "as it
4 pertains to your pharmaceutical drugs and the packaging for
5 pharmaceutical drugs?

6 A. Yes, yes.

7 Q. What is a vignette?

8 A. A vignette is something that's unique in the French
9 market for drugs. When pharmaceuticals are produced in France
10 and sold in the French market, such as this Plavix for
11 example, if this is being sold in the French market or was
12 available in the French market, it would have a sticky label
13 attached to it. The sticky label is called a vignette. It is
14 roughly the same size as that bar code that can be seen on the
15 packing. The vignette itself has the appearance of a bar
16 code. As I say, it's removable when it's stuck to a package.
17 And the purpose for having a vignette on the package is purely
18 for the French market and it's for tax reasons and for
19 reimbursement of funds. When pharmacists are involved in the
20 sale, the vignette comes into play. The vignette gets removed
21 and money is claimed within the French system. It's purely
22 unique to the French market. So any drugs coming out of
23 France, for example, on a parallel import, which we discussed
24 earlier, would have a vignette affixed to it.

25 Q. So if this Plavix that you have in front of you that's

1 being displayed to the jury, if this Plavix were purchased in
2 France, it would -- should have a vignette or a label or
3 sticker attached to it that's required by the French
4 Government; is that correct?

5 A. That's correct, it would have a label, a vignette label,
6 on it.

7 Q. And where would that label appear on a carton such as
8 this one?

9 A. It would appear on the back on the wide side.

10 Q. On the box that you have and the box that's being
11 displayed to the jury, do you see a vignette on either of the
12 two boxes?

13 A. No, there's no vignette on this box or any of the boxes.

14 Q. In the evidence bag that's in front of you, can you take
15 a moment and look through the bag and see if you see vignettes
16 on any of these cartons?

17 A. There's no vignette displayed on any of these packages.

18 Q. Thank you. I will next show you what's already been
19 admitted into evidence as Government's Exhibit No. 25-B, as in
20 boy. And this is an evidence bag containing several boxes of
21 Casodex. I'm going to ask you the same type of question. Let
22 me display this box for the members of the jury. Mr. Jones,
23 do you have that box in front of you?

24 A. Yes.

25 Q. Is that a box of Casodex -- or what purports to be a box

1 of Casodex?

2 A. Yes.

3 Q. 50 milligrams, is that what's on front of the box?

4 A. Yes, sir.

5 Q. And the manufacturer at the bottom right-hand corner is
6 AstraZeneca?

7 A. Yes, sir.

8 Q. If you look at the front above the name Casodex, does it
9 appear to have French language at the top of the box?

10 A. That's also correct, sir, yes.

11 Q. I'm going to turn the box over and I'll ask that you do
12 the same with the box that you have. And do you see a red box
13 surrounding some white spaces in the back of the box?

14 A. Yes, sir.

15 Q. Do you see -- take a moment and examine the box. Do you
16 see a bar code on the side of the box that you have in front
17 of you?

18 A. Yes, I do.

19 Q. Is that a vignette there?

20 A. No, it's not.

21 Q. Well, look at the entire box, front, back and all the
22 sides and tell me if you see a vignette anywhere on the box
23 that's in front of you.

24 A. No, there's no vignette. The vignette is a completely
25 separate sticky label.

1 Q. Is it a label that is affixed after the box has been
2 made; is that correct?

3 A. That is correct. It would also have the amount of money
4 that the French Government want to claim actually written on
5 the vignette.

6 Q. If you can briefly explain the significance of the
7 vignette. What does that mean to someone buying
8 pharmaceutical drugs that are made in France? What does a
9 vignette represent?

10 A. It is a way of the French government taxing money as a
11 result of the sales of medicines. The vignette creates that
12 money for the pharmacists. And on the vignette itself it will
13 dictate exactly how much money is to be claimed by the
14 pharmacist for tax purposes. I don't fully understand the
15 exact reason for it, but what I do know is that it's unique to
16 the French market. And any products that are in France for
17 sale have a vignette on it. Any products coming out of France
18 being on the French market or being available to be on the
19 French market will have a vignette on it.

20 Q. If I am a parallel importer or a consumer in France, what
21 is the significance of the vignette concerning the
22 authenticity of the product?

23 A. It shows that the product was -- originated or was on the
24 market for sale in France.

25 Q. Let me ask you to take a moment and look through the

1 entire evidence bag of Government 25-B containing several
2 boxes of Casodex and tell me if you find any boxes that has a
3 vignette attached.

4 THE COURT: For purposes of time, I assume you've
5 already looked at them; is that correct, Mr. Lewis?

6 MR. LEWIS: Yes, I have, Your Honor.

7 THE COURT: And there are no vignettes?

8 MR. LEWIS: That's correct.

9 THE COURT: All right. Let's -- does the defense
10 think there are any vignettes in the box?

11 MR. AMANN: We have no objection to --

12 THE COURT: All right.

13 MR. AMANN: I'm sorry.

14 THE COURT: Sorry, Mr. Buckley, you can't cross him.

15 BY MR. LEWIS:

16 Q. Finally, Mr. Jones, let me show you what's been admitted
17 into evidence as Government's Exhibit No. 4, the evidence bag
18 containing several empty cartons of Zyprexa. I'm going to
19 leave one copy with you and I'm going to display one copy for
20 the members of the jury. And you see this says Zyprexa.

21 Who's the manufacturer, according to this carton, sir?

22 A. This is Eli Lilly.

23 Q. And what is the dosage amount on the front of the carton?

24 A. Let's see, it's 10 milligrams, sir.

25 Q. Does this language also appear to be French?

1 A. That's also correct, sir, yes.

2 Q. Looking at the back of the carton, do you see a red box
3 and white spaces enclosed within the red box?

4 A. Yes, I do, sir.

5 Q. And if you look at the side, all sides of the carton
6 that's in front of you, do you see a vignette on the box
7 that's in front of you?

8 A. There's no vignette on this box.

9 Q. Finally, Mr. Jones, let me show you what's been admitted
10 into evidence, Government's Exhibit No. 31. This is the
11 bottom right-hand corner of Government's Exhibit No. 31. It
12 is a series of emails on a Yahoo account. Turning to the
13 third page of Government's Exhibit 31, let me ask you -- let
14 me hand it to you to make it easier. There are two dates on
15 Page 3 for these two emails. Let me ask you if you can read
16 to the members of the jury the two dates that appear on this
17 third page of the emails?

18 A. This is the 25th of May 2007.

19 Q. And what's the date at the top?

20 A. Also 25th of May 2007.

21 Q. Okay. Thank you. If you can read along with me,
22 Mr. Jones, I have a question for you.

23 A. The bottom email says:

24 "Hello Kevin:

25 "One of my customers called and said there is a

1 recall of Zyprexa in Europe with the same lot number. I am
2 trying to find out more on the internet. Have you heard
3 anything? We will cancel Zyprexa order until we find out the
4 problem lot number. Please inform me if you find something."

5 Sir, the date of that email is May 25th, 2007; is
6 that correct?

7 A. That is correct, sir, yes.

8 Q. Then at the top there's a response by Kevin Xu also dated
9 May 25th, 2007, where he states:

10 "Hello Kevin:

11 "Okay, no problem. I do not think this will impact
12 us because we have not sold to europe per your request. I
13 will let u know if I hear more and will you please do the
14 same."

15 Let me next show you the recall notice, Government's
16 Exhibit No. 32, for Zyprexa, the same drug that's discussed in
17 the email. What is the date of this recall notice, sir?

18 A. 24th of May 2007.

19 Q. That is one day before May 25th, 2007, this email traffic
20 between Mr. Xu and the undercover agent in this case; is that
21 correct?

22 A. That's correct.

23 MR. LEWIS: I pass the witness at this time.

24 THE COURT: Mr. Buckley, you may proceed.

25 MR. BUCKLEY: Thank you, Your Honor.

1 CROSS-EXAMINATION

2 BY MR. BUCKLEY:

3 Q. Good afternoon, Mr. Jones.

4 A. Good afternoon.

5 Q. My name is Sean Buckley. I'm one of Mr. Xu's lawyers.

6 You spoke briefly, Mr. Jones, about parallel trading and how

7 it works in and out of the UK. You're aware that parallel

8 trading is something that operates in the entire European

9 economic area; correct?

10 A. That's correct, sir, yes.

11 Q. And do you know off the top of your head how many

12 countries are in the European economic area?

13 A. I'd be guessing, sir.

14 Q. If I show you a list to refresh your recollection?

15 MR. BUCKLEY: May I approach, Your Honor?

16 THE COURT: Sure.

17 BY MR. BUCKLEY:

18 Q. I don't want to suggest to you that these are the

19 countries, but if you would look and, based on your

20 independent knowledge, if you could tell me if that list is

21 correct.

22 A. Most of those countries, definitely in the European

23 community, yes.

24 Q. That's, approximately, 20 or 25 countries in there?

25 A. Yes, correct.

1 Q. Thank you, sir. Now, the regulations that apply to
2 distribution of pharmaceuticals within the UK do not
3 necessarily apply, do they, to distribution of pharmaceuticals
4 in other EEU countries; is that correct?

5 A. That's not correct, sir, no.

6 Q. Okay.

7 A. The guidelines and the regulations and the issuance of
8 licenses are all very similar throughout Europe, hence, the
9 countries would trade with each other.

10 Q. Now, in the -- in the recall reports I know that y'all
11 did a -- whether it's a market analysis or part of your
12 investigative effort that identified the parallel importers or
13 the parallel marketers that were involved with each of the
14 drugs; is that --

15 A. I wasn't the one to do the actual recall. I can't really
16 assist you.

17 Q. Okay. Well, do you know from your own knowledge whether
18 there were in about May of 2007 approximately 40 UK parallel
19 distributors who were handling Zyprexa?

20 A. I don't.

21 Q. Okay. Do you have any knowledge of how many parallel
22 distributors would handle Zyprexa over the whole European
23 economic area?

24 A. I don't, sir, no.

25 Q. But if an individual was distributing a particular

1 pharmaceutical in the UK, for example, that wouldn't
2 necessarily mean they would be distributing all over the EEU?

3 A. That's correct.

4 Q. Okay. In the overall parallel trading, parallel
5 distribution model, because of, perhaps, economic inequities
6 among the countries, one can pluck pharmaceuticals from the
7 supply chain, perhaps, from any country and then under the
8 right set of circumstances move it and market it in another
9 country within the EEU; is that the basic premise of how this
10 works?

11 A. If they're licensed in the correct manner, yes.

12 Q. So it is -- and my understanding, also, is that you no
13 longer have to parallel market or parallel distribute from a
14 common source since 2004. Do you know?

15 A. I don't fully understand the question, sir.

16 Q. I think my question is -- and I'm not an expert -- is
17 that in order to distribute a particular pharmaceutical around
18 the EEU as a parallel distributor, you're not required to --
19 for all the parallel distributors to get the pharmaceutical
20 from the same source; is that fair to say?

21 MR. LEWIS: I'm going to object to that, Your Honor,
22 given that he hasn't established that this witness has
23 expertise in parallel importers outside of the UK. He
24 certainly is familiar with the procedures and the legal
25 requirement within the UK. He's asking about the entire --

1 THE COURT: See if you can establish a foundation for
2 the witness to respond.

3 MR. BUCKLEY: Yes, Your Honor.

4 BY MR. BUCKLEY:

5 Q. In your responsibilities as an -- in an investigative
6 capacity, you have been educated and trained in the workings
7 of parallel distribution within the EEU in general terms;
8 correct?

9 A. Yes, sir.

10 Q. And that training and that education is geared towards
11 being an effective investigator within the UK and
12 understanding how all this works in a broader scheme?

13 A. That is also correct, yes.

14 Q. And based on that knowledge and understanding, it is then
15 your observation, based on your personal knowledge, of how
16 parallel distribution works in the EEU that one does not have
17 to get their product to distribute it from a common source,
18 one could, say, pluck out of the supply chain, say, out of
19 Romania and then market in Finland; is that fair to say?

20 A. I don't really think that is fair to say, no.

21 Q. What is your understanding of how -- of the limitations
22 of parallel distribution in terms of where you can source the
23 material from and how far you can distribute it?

24 A. Well, initially you can only purchase drugs, say, from
25 France, as I mentioned earlier, if you have correct licenses

1 within the UK and also current licenses in France. So if
2 neither is in place, then it can't be completed.

3 Q. Now, your understanding, though, is that, nevertheless, a
4 French product could, under some circumstances, be parallel
5 marketed or parallel distributors in other countries within
6 the EEU, not just the UK; correct?

7 A. That's correct, yes, sir. My department of MHRA is
8 purely investigation. So I'm making observations on what
9 you're saying regarding that. I can't be completely sure, but
10 it does sound as though you're probably correct, yes.

11 Q. I understand. Do you know a man named Terrence Blackett?

12 A. I heard that name, yes.

13 Q. What is your knowledge of who Mr. Blackett is?

14 A. Someone being in touch with Mr. Xu on email.

15 Q. Is he, to your knowledge, an employee of a pharmaceutical
16 company or do not know? If you don't know, that's okay.

17 A. I don't know. From the inquiries made, Mr. Buckley,
18 prior to coming to this Court, I believe he's not a license
19 holder.

20 Q. Now, in these recalls that we've discussed, who requested
21 the recall, was it the manufacturer or was it an agency such
22 as your agency?

23 A. The MHRA.

24 Q. Now, you had mentioned observing some photographs that
25 were taken from Mr. Xu's computer.

1 A. Yes.

2 Q. In the course of your investigation, did you undertake to
3 try to determine the original source of those photographs?

4 A. That is part of an ongoing investigation.

5 Q. But at this point you still have not identified with
6 certainty the source of those photographs?

7 A. No. They're on the laptop.

8 Q. And in connection with that, you don't know one way or
9 the other whether those photographs originated on Mr. Xu's
10 laptop or whether they came from some other source, perhaps
11 electronically transmitted?

12 A. I haven't examined the laptop myself in that depth. I
13 believe they were attachments to emails. Whether they were in
14 or outside, I can't recall.

15 Q. We talked about -- or you testified about the lot numbers
16 that were specified in the recall notices. In connection with
17 your investigation, did you identify the number of pills
18 associated with each respective lot number in the marketplace
19 per the manufacturer, if you understand my question?

20 MR. LEWIS: I'm going to object because I don't
21 understand it.

22 THE COURT: I don't understand it either.

23 MR. BUCKLEY: Thank you, Your Honor. I will do my
24 best to simplify.

25

1 BY MR. BUCKLEY:

2 Q. In connection with your investigation and your work with
3 the manufacturers, did you investigate how -- what the volume
4 of each particular lot number was in the marketplace?

5 A. What I can say, sir, is that it was 70,000 packs in total
6 of the three drugs involved, of which 30,000 to go to the
7 pharmacy, but to split them into three, I can't give you exact
8 figures.

9 Q. And there's no real indication, is there, about the
10 geographic spread of these products, for example, which EEU
11 countries they may have ended up in or flowed through, Is
12 There?

13 A. I think they were made in the UK.

14 Q. Made in the UK?

15 A. Mainly just made in the UK.

16 Q. Do you know as a result of the recall how many
17 distributors worldwide were affected?

18 A. I don't, sir, no.

19 Q. You testified about the vignettes on the French products.
20 And my understanding is that the vignette is applied via
21 sticker --

22 A. That's correct.

23 Q. -- is that correct?

24 And this is not embossed into the product box or
25 anything like that?

1 A. It's not.

2 Q. So it can be removed?

3 A. Yes, with difficulty.

4 Q. And the vignette system began in 1997 or do you know?

5 A. I don't know, sir.

6 Q. Okay. Do you know if, in general practice, whether
7 materials or pharmaceuticals which are produced in France that
8 then went to parallel distributed in various other countries,
9 in the course of doing that, those vignette labels could be,
10 as a matter of course, from some distributors removed?

11 A. My understanding is different, sir. My understanding is
12 that if the vignette is on the package shows that the drugs
13 originated from France. If the vignette was not on the
14 package, it couldn't be established.

15 Q. Now, if a parallel distributor is taking the French
16 products in the French box with the French vignette and which
17 is to remarket, for example, in Romania, the person would
18 usually undertake some form of repackaging; correct?

19 A. Yes. The normal practical way in the UK, for example,
20 would be to stick the sticky label I mentioned earlier, which
21 outlines the tablets and directions for use actually on top of
22 the vignette.

23 Q. And the reason for -- well, the reason for repackaging,
24 in any event, would be that if you introduce into the
25 marketplace of one country with one language a product that

1 was developed and marketed in a different country with a
2 different language, you wouldn't really be able to access the
3 marketplace very well, would you? In other words, the
4 customer probably would not want to buy in Romania a product
5 that was written in Dutch that had the instructions and the
6 labels in Dutch; fair to say?

7 A. Well, of course one would have to understand what one was
8 reading on the leaflet.

9 Q. And also understand what it was they were purchasing in
10 the store?

11 A. Yes.

12 Q. And whereas there are common standards in the EEU for
13 parallel distribution, each country may have their own
14 particular practices as to how this is done or what is
15 tolerated and what is not tolerated; fair to say?

16 A. It's fair to say that all countries are fully aware of
17 any products France would have vignettes on them and would not
18 purchase a product without a vignette.

19 Q. Okay. Of course, you can't speak to the particular
20 normal practices of the market, the consumer market in
21 Romania, can you?

22 A. I can't make comments on that at all.

23 MR. BUCKLEY: May I have a moment, Your Honor?

24 THE COURT: Yes.

25 MR. BUCKLEY: Thank you, Mr. Jones. Pass the

1 witness.

2 MR. LEWIS: A couple of questions, Your Honor.

3 REDIRECT EXAMINATION

4 BY MR. LEWIS:

5 Q. Mr. Jones, did I understand your testimony correctly that
6 of the three drugs that are listed in the recall notices
7 roughly 70,000 of those packages or packs were entered into
8 the legitimate drug supply in the UK; is that correct?

9 A. That is correct, yes.

10 Q. And if I heard you correctly, roughly 30,000 of those
11 packs went to pharmacies within the UK.

12 A. That's also correct, yes.

13 MR. LEWIS: No further questions. Thank you.

14 THE COURT: May the witness be excused?

15 MR. LEWIS: He may, Your Honor.

16 MR. BUCKLEY: Yes.

17 THE COURT: Thank you, Mr. Jones.

18 Counsel, approach the bench.

19 (A bench conference was held outside the presence of
20 the jury.)

21 THE COURT: How many more witnesses do you have?

22 MR. LOUIS: Two or three people.

23 THE COURT: Are they all drug people.

24 MR. LOUIS: Two are drug people and one is an agent
25 on the issue of wholesaling.

1 THE COURT: The issue of what?

2 MR. LOUIS: Wholesaling.

3 THE COURT: Okay. So we might -- are you ready to
4 start this afternoon?

5 MR. AMANN: I don't think my witness is getting into
6 town until late this evening.

7 THE COURT: You said you had four people.

8 MR. AMANN: I think out of those four we're probably
9 just going to have one.

10 THE COURT: Is Mr. Xu going to testify?

11 MR. AMANN: At this point I would say no.

12 THE COURT: All right.

13 (Bench conference concluded.)

14 THE COURT: We'll take a 15-minute recess, ladies and
15 gentlemen. We'll stand in recess until 2:40.

16 (A recess was taken.)

17 MR. LEWIS: The United States calls Dr. Christin
18 Nielsen.

19 THE COURT: Come around, ma'am, to be sworn as a
20 witness.

21 DR. CHRISTIN NIELSEN

22 having been first duly sworn, testified as follows:

23 THE COURT: Be seated, please.

24 All right. Mr. Lewis, you may proceed.

25 MR. LEWIS: Thank you, Your Honor.

1 DIRECT EXAMINATION

2 BY MR. LEWIS:

3 Q. Good afternoon. Could you please state your full name
4 and spell your first name and last name for the members of the
5 jury, please.

6 A. Yes. My full name is Christin Feretta Nielsen. My first
7 name would be C-h-r-i-s-t-i-n. My last name is N-i-e-l-s-e-n.

8 Q. How are you employed?

9 A. I'm a pharmacist and I'm employed at Hoffmann-La Roche
10 Pharmaceutical Company.

11 Q. Can you spell the name of the company that you work for?

12 A. R-o-c-h-e.

13 Q. And I believe you mentioned Hoffmann Roche; is that
14 correct?

15 A. Hoffmann-La Roche, yes, that's correct.

16 Q. La Roche. And can you spell Hoffmann, please?

17 A. H-o-f-f-m-a-n-n.

18 Q. What type of company is Roche?

19 A. It is a pharmaceutical company.

20 Q. Where is your office located?

21 A. My office is locate in Kaiseraugst in Switzerland.

22 Q. Can you spell Kaiseraugst, please.

23 A. K-a-i-s-e-r-a-u-g-s-t.

24 Q. How long have you worked for Roche?

25 A. I have worked for Roche for approximately five years,

1 since 2003.

2 Q. Can you tell us briefly about your education? Did you
3 attend university?

4 A. Yes. I have a degree in pharmacy from the University of
5 Bologna in Italy, yeah.

6 Q. And are you considered a -- to be a Ph.D. or doctor in
7 the field of biology or chemistry?

8 A. Yes, I've a doctorate in pharmacy and I have specialized
9 in applied biochemistry, microbiology and applied analytical
10 chemistry.

11 Q. So it is appropriate if I were to refer to you as
12 Dr. Nielsen; is that appropriate?

13 A. Yes, it is.

14 Q. Tell us your position, please, with Roche.

15 A. I am working as a complaint manager. We are coordinating
16 the negotiations of technical complaints from the market and
17 also investigations of suspected counterfeits where they use
18 the same structures because we have connections with the
19 laboratories and all the other departments.

20 Q. Just by way of example, if a suspected counterfeit sample
21 is sent to you, what's the process? What do you do with that
22 sample?

23 A. The sample is sent directly to me. I open the sample, I
24 look at it, I -- the first thing I do, I check the variable
25 data on the sample, which would be only on it if we've got the

1 packaging material, variable data would be the lot number of
2 the product, the manufacturing date and the expiry date of the
3 product. So I see if the lot number on the material, if we
4 have an original product with the lot number. And I also
5 check if the manufacturing date and expiry date corresponds to
6 the manufacturing date and expiry date of the original
7 product.

8 Q. A sample, a suspected sample of a counterfeit product,
9 who would send that sample to you, where does it come from?

10 A. It comes from another country, from our affiliate in the
11 country where it was found.

12 Q. And let me show you what's been marked for identification
13 purposes as Government's Exhibit 54, actually two plastic bags
14 that have been stapled together and let me ask you, have you
15 seen the contents of these two plastic bags prior to today?

16 A. Yes, I have.

17 Q. And what's contained in those two plastic bags?

18 A. Each of the plastic bags contain one blister card with
19 inside some capsules. That seems to be Tamiflu, which is our
20 product.

21 Q. Tamiflu is a product of Roche?

22 A. Yes, it is.

23 Q. It's a product that's manufactured and made by Roche; is
24 that correct?

25 A. Yes, it is .

1 Q. Were those samples sent to you, sent to Roche for
2 investigation?

3 A. They were.

4 Q. Were those samples received by you?

5 A. Yes, they were.

6 Q. And how do you know that they were received by you?

7 A. Because when I receive a sample I -- what we do, also,
8 for investigation, we log the case into a database so it has a
9 number. And I put the sticker on the sample, writing the
10 number, the registration number, the date when I received the
11 sample and I signed with my signature on the label. And I see
12 that here.

13 Q. Okay. And there are two bags. Do you see two stickers,
14 one for each bag?

15 A. Yes, I do.

16 Q. And those are stickers that you placed on the bags when
17 you received these samples; is that correct?

18 A. Yes, they are.

19 Q. There appears to be some handwriting in addition to your
20 initials, there are numbers on each of the stickers. What's
21 the top number for, the first sticker?

22 A. The number on the first sticker, 36270.

23 Q. And the sticker on the second bag, what is that number?

24 A. That number is -- sticker on the second bag is 38120.

25 Q. Is that a number that you placed on the sticker?

1 A. Yes, it is.

2 Q. And what is the importance or significance of those
3 numbers?

4 A. Being able to track the investigation, the samples, where
5 they go.

6 Q. Of those two bags, which one did you receive first?

7 A. The one with the lowest number and I have the date on
8 them as well. So it is the 36270.

9 Q. And when did you receive it? What is the date?

10 A. The 10th of May 2007.

11 Q. And what is the date on the second sticker?

12 A. The 12th of June 2007.

13 Q. Okay. And these were sent to you to be tested to see if
14 they were authentic or counterfeit; is that correct?

15 A. Yes, that's correct.

16 MR. LEWIS: At this time the Government would offer
17 Government's Exhibit No. 54 into evidence.

18 MR. AMANN: Just one quick question, if I could, Your
19 Honor.

20 THE COURT: All right.

21 MR. AMANN: Dr. Nielsen, where did you receive these
22 samples from, do you know? Is there any piece of paper here
23 that says where they came from?

24 THE WITNESS: There is not on there. I received it
25 directly from our affiliate in Nutley. It doesn't say on this

1 bag.

2 MR. AMANN: It doesn't say where it comes from. Do
3 you have a report that tells us where these samples came from?

4 THE WITNESS: I have in my documentation a piece of
5 paper where it says where it comes from, who sent me the
6 sample.

7 MR. AMANN: May I just speak with the prosecutor a
8 moment?

9 (Discussion was held off the record.)

10 MR. AMANN: I have no objection, Your Honor.

11 THE COURT: All right. Government's Exhibit 54 is
12 admitted.

13 BY MR. LEWIS:

14 Q. Dr. Nielsen, let me hand to you Government's Exhibit
15 No. 54 and ask you when you received these two samples -- and
16 we'll start with the lowest one first that has the No. 36270
17 on the sticker, what did you do with that sample when you
18 received it? What's the first thing that you did?

19 A. Well, I take the sample out and look at it and look at
20 the variable data.

21 Q. The variable data?

22 A. Yes.

23 Q. What does that mean? What did you look at?

24 A. That says which lot number it is, it says the
25 manufacturing date of the product and the expire date of the

1 product.

2 Q. When you received these samples, was there a carton or a
3 box or did you receive only the blister packs?

4 A. No, we received only the blister pack.

5 Q. Did the blister packs have the lot number, the
6 manufacturer and the expiration date, is that information
7 captured on the blister packs that you received?

8 A. Yes.

9 Q. And for the first sample, what was the lot number or what
10 is the lot number? If you can't read it, we can take it out
11 of the bag.

12 A. Yeah, it is quite hard readable, but I manage to read it.
13 It is B1117.

14 Q. Is there an expiration date?

15 A. Yes, there is. It says 04-2010.

16 Q. Is there information about who the manufacturer is, the
17 name of the manufacturer on the package?

18 A. No, there's no -- it doesn't say who the manufacturer is.

19 Q. Tell us what information, other than the expiry or the
20 expiration date and the lot number, what information can you
21 read from the blister pack? Is the name of the drug there?

22 A. Yes, I see also MFD, which would be manufacturing date.
23 But the date is not readable on this sample. Then I see the
24 name Tamiflu --

25 Q. Tamiflu is there.

1 A. -- which is the name of our product. Beneath that is
2 written oseltamivir, which would be the API in the product.

3 Q. API is the active pharmaceutical ingredient?

4 A. Correct, yes. And then it says 75 milligrams, which
5 would be the strength.

6 Q. How many tablets are contained or should be contained in
7 the blister pack that you have in front of you?

8 A. There should be ten capsules in it, if it's complete.

9 Q. So when you looked at the variable data, what did you
10 conclude, if anything, after you looked at the variable data
11 on the sample?

12 A. I checked the data in the system and I saw it corresponds
13 to our original lot B1117 and that expiry date would be as the
14 original product. Although the imprint embossing off the
15 expiry date, it seems strange to me because ours is more clear
16 and bigger so it's better readable.

17 Q. Okay. Anything else?

18 A. Yes. When I looked at the imprint of Tamiflu on the
19 blister foil, I see they are all -- the writing is all in one
20 line, on the same line, which I wasn't sure that that was
21 right because normally they are not on one line but one up,
22 the other down, next up. So it's, like, on two lines like
23 this.

24 Q. As you were doing your analysis, your visual analysis of
25 the sample, did you have a reference product or an authentic

1 product blister pack to compare it against?

2 A. Now, what we do to be sure -- that was just what I saw at
3 first glance. When -- to be sure that it is original or not,
4 I forward the packaging material to our quality control
5 packaging material and ask them to compare the packaging
6 material with the packaging material of the original product.
7 So I send it to these experts and have them verify the
8 packaging material, compare to the original packaging
9 material.

10 Q. Did you at some point in time on your own compare the
11 original packaging material with the sample?

12 A. Yes, I did.

13 Q. And based upon your comparison of the two, of the sample
14 and the original blister pack, what did you observe from your
15 observations about the name Tamiflu and how it appeared on the
16 sample and how it appeared on the original?

17 A. That -- that my first impression was correct, that it is
18 different from our product, our product looks different.

19 Q. Okay. I'm going to take -- which one is the first one,
20 this one?

21 A. This one is the first one.

22 Q. I'm going to take it out of the bag so we can show it to
23 the members of the jury. And while I'm doing that I'm going
24 to ask you to explain how the name Tamiflu is different on the
25 sample as compared to the authentic blister pack. I believe

1 you just testified that the word Tamiflu appears in a straight
2 line on this sample; is that correct.

3 A. Yes, that's correct.

4 Q. And how is that different from the authentic or the
5 original?

6 A. The original would be every second Tamiflu writing would
7 not be on the same line, but below. So they are not in a line
8 but -- I don't know how to word it.

9 Q. I believe you just testified that the word Tamiflu would
10 be up on one tablet and then down on the next tablet; is that
11 right?

12 A. Yes, it's like a -- Tamiflu, Tamiflu, Tamiflu.

13 Q. In your observations about the sample, did you notice
14 anything else that was different from the original other than
15 the name Tamiflu as it appears on the sample?

16 A. Yes, I did. The field where the variable data is written
17 on the blister, it's a field you see on the right side. It is
18 smaller than on the original sample and also the writing is
19 different.

20 Q. I'm going to try to point this out to the members of the
21 jury, if I can. Is this the field for the variable data that
22 you're testifying about?

23 A. Yes, it is.

24 Q. And with the sample it is smaller than as compared to the
25 original; is that correct?

1 A. The sample is smaller, yes.

2 Q. The field is smaller?

3 A. The field is smaller.

4 Q. And what information is contained in the field?

5 A. The lot number, the manufacturing date and the expiry
6 date -- expiration date.

7 Q. Did you notice anything else that was different?

8 A. Yes, I did. When you compare this sample to our original
9 product -- I don't know if you can see it here -- there are
10 like a perforated line or there should be in order that you
11 can divide every single blister pocket from the blister. And
12 here you see it's -- that there should be something. Our
13 original product is really clear.

14 Q. Okay.

15 A. And there's one thing more that I saw.

16 Q. Please share with us.

17 A. When you seal the blister, the pattern that you get on
18 the blister foil -- on this blister here, it looks like it's
19 been sealed with plate sealing. And on the original product,
20 the pattern is different. And it comes from typical rolled
21 sealing. So the machine is different for the sealing which
22 has been used for this one and which has been used for the
23 original.

24 Q. So for this sample it is your opinion that this -- the
25 plate sealing was done as compared with the original --

1 explain that to me once again. I'm getting confused.

2 A. The pattern, which is on the -- what you see here on the
3 foil --

4 Q. Yes.

5 A. -- is different on the two samples, the original sample
6 and on this sample. This pattern we see here would be typical
7 for plate sealing because it's, like -- it has points which is
8 going to be bored in. You see the holes. We use a machine
9 for packaging the original product, which is a different
10 sealing system. It's a roll sealing. And there the pattern
11 is, like, not holes being burn in but it's more like lines
12 that are sealed on.

13 Q. Based upon your observations, did you suspect that this
14 sample was counterfeit?

15 A. Yes.

16 Q. Did you refer this sample to your chemistry lab for
17 chemical analysis?

18 A. Yes, I did.

19 Q. Do you know who Dr. Anton Fischer is?

20 A. Yes, I know.

21 Q. And who is Dr. Fischer?

22 A. Dr. Fischer is one of my colleagues at the quality
23 control and they are doing analytical investigations. They
24 are doing it, for example, in our lab, HPLC.

25 Q. Did you send this sample to Dr. Fischer for an analytical

1 or chemical analysis?

2 A. Yes, I did.

3 Q. What was your conclusion about this sample? Was this
4 sample counterfeit or was it authentic?

5 A. This sample is counterfeit. It's not a Roche product.

6 Q. Let me show you the next sample which has the complaint
7 number -- the Roche Complaint No. 38120 and ask you,
8 briefly -- let's take it out of the bag so you can see it
9 clearly -- did this sample have similar -- let me ask a
10 different question. What did you observe about this sample?
11 Let's start with the variable data.

12 A. It is -- it is very -- it's smaller area. It looks
13 smaller in the area than our original product. The writing,
14 it says expire date, the XP 04-2010. And it says the lot
15 number is B1117. Then it says MFD and I'm not able to read.

16 Q. The manufacturing date?

17 A. Yes.

18 Q. As with the first sample, did you also observe that the
19 word Tamiflu appears in a straight line and not in an up and
20 down pattern --

21 A. Yes.

22 Q. -- as is found with the authentic product?

23 A. Yes.

24 Q. Did you find similar differences with the way that this
25 sample was sealed as compared with the authentic product?

1 A. Yes, the same for this. It looks like a plate sealing,
2 not like a rolled sealing.

3 Q. And did you also observe -- I think you just testified
4 about this -- that the variable data field is smaller on the
5 sample as compared with the authentic?

6 A. Yes.

7 Q. Did you also send this sample to Dr. Fischer for chemical
8 analysis?

9 A. Yes, I did.

10 Q. Did you compare this sample with the authentic product so
11 that you could observe the differences?

12 A. Yes, I did.

13 Q. And based upon the testing of the second sample, did you
14 conclude that the second sample was also counterfeit?

15 A. Yes, I did.

16 Q. Does the lot number for a product for Tamiflu -- does a
17 lot number tell you where the product was manufactured?

18 A. Yes, it does. "B" stands for Basel in Switzerland.

19 Q. How is that spelled, B-a-s-e-l; is that correct?

20 A. B-a-s-e-l.

21 Q. Okay. So Lot No. B117, is that a lot number that has
22 been used by Roche for the production of Tamiflu?

23 A. Yes, it is.

24 Q. Okay. And in the year 2007, did Roche manufacture or
25 produce Tamiflu in China?

1 A. No, they did not.

2 Q. In 2007, do you know where Tamiflu was packaged and
3 manufactured?

4 A. I can tell you about the concerned lot number.

5 Q. Yes, B117, which is the number that's found on two
6 samples.

7 A. Yes.

8 Q. Were those -- using that lot number, were any of those
9 Tamiflu products manufactured in China?

10 A. No.

11 Q. And where were they manufactured?

12 A. They were manufactured -- manufacturing of the capsules
13 was in Basel in Switzerland. Then the lot was packaged in
14 Kaiseraugst in Switzerland and some captures of this lot
15 number went to Brazil where they were also packaged.

16 Q. Is Tamiflu a registered product of Roche?

17 A. Yes, it is.

18 Q. Do you know when Tamiflu first became a product -- a
19 registered product of Roche? Do you know the year?

20 A. No. It depends on which country. Now, for the U.S. the
21 first date of use was in November 2 -- November 1999.

22 Q. November 1999?

23 A. Yes, November 1999.

24 Q. And that was the date of first use in the United States?

25 A. Yes, that's correct.

1 MR. LEWIS: May I have a moment, Your Honor?

2 THE COURT: Yes.

3 MR. LEWIS: We'll pass the witness at this time, Your
4 Honor.

5 THE COURT: All right. Mr. Amann.

6 MR. AMANN: Thank you, Judge.

7 CROSS-EXAMINATION

8 BY MR. AMANN:

9 Q. Dr. Nielsen, good afternoon.

10 A. Good afternoon.

11 Q. How are you today?

12 A. Fine, thank you.

13 Q. You're from Switzerland?

14 A. No, I'm from Denmark.

15 Q. You're from Denmark. English is not your first language?

16 A. No, it's not.

17 Q. What is your first language?

18 A. Danish.

19 Q. Danish. When you're trying to speak English, sometimes
20 you have trouble searching for the right word --

21 A. It could happen, yes.

22 Q. -- now and again.

23 Now, with respect to Lot No. 1117, you have that lot
24 number in your Roche database, is that true?

25 A. In which Roche database?

1 Q. I think you made some reference to a database that you
2 were referring to?

3 A. Yes, that's correct. In the complaint database we have
4 suspected counterfeit cases, yes, we have it in there.

5 Q. All right. With respect to Lot No. B1117, can you tell
6 us how many Tamiflu pills were made by Roche that has that lot
7 number, do you know?

8 A. I'm not sure I understand your question.

9 Q. Okay. A lot number has many pills in it. Okay. What
10 I'm trying to figure out is how many pills are in that lot
11 number, B1117.

12 A. No, I don't know.

13 Q. All right. Are you familiar, Doctor, with how Tamiflu is
14 made, the chemical process as a pharmacist?

15 A. I don't know every single step. I know in general what
16 Tamiflu is.

17 MR. AMANN: All right. May I approach, Your Honor?

18 THE COURT: Yes.

19 BY MR. AMANN:

20 Q. For demonstrative purposes I'll ask you if you can just
21 recognize some of that chemistry that's going on there.

22 A. Uh-huh.

23 Q. Just take a moment and review it and see if that is
24 familiar to you as to how Tamiflu is produced, the chemical
25 process that goes into putting it altogether.

1 A. I don't think I'm the right person for saying anything
2 about this.

3 Q. Okay. So that's something you don't feel competent to
4 talk about?

5 A. Yes.

6 Q. All right. Very good. With respect to -- let's talk
7 about this exhibit for a moment. Now, this box right here, is
8 that part of an exhibit or is that what you brought with you?

9 A. I brought that with me.

10 Q. Okay. So this box right here is not a part of any
11 Government exhibit, it didn't come out of any pack?

12 A. No, no, no, I took it with me from Switzerland.

13 Q. From Switzerland. And it is the real Tamiflu?

14 A. Yes, it is.

15 Q. All right. If I -- do you mind if I look at this?

16 A. No, of course not, go ahead.

17 Q. Now, is this the Tamiflu that's marketed in the United
18 States?

19 A. No, it's not.

20 Q. Do you know where this box that you brought, where it is
21 marketed?

22 A. Yes, I know. New Zealand, this one.

23 Q. New Zealand. If you know, how many production factories
24 does Roche have around the world that make Tamiflu?

25 A. That makes Tamiflu?

1 Q. Just makes it, not markets it or packages it, produces
2 it.

3 A. I don't know the exact number, but it's not many.

4 Q. Do they have some in Europe?

5 A. Yes.

6 Q. And New Zealand apparently?

7 A. No.

8 Q. And not New Zealand. Okay. They have a distributor in
9 New Zealand?

10 A. Yes.

11 Q. So they have companies that make it and then they also
12 have companies that package it and distribute it?

13 A. Yes.

14 Q. Okay. Two separate deals. All right. Now, with respect
15 to how many companies they have around the world that package
16 it, do you have any idea?

17 A. It's not many. We package most of it in Basel. Now
18 Brazil was packaging some as I told you. There are a few
19 others, but I don't know exactly how many.

20 Q. Okay. May I borrow this?

21 A. Yes, please.

22 MR. AMANN: Judge, for demonstrative purposes may I
23 use what the witness has identified as genuine Tamiflu?

24 THE COURT: Sure.

25

1 BY MR. AMANN:

2 Q. Okay. I just want to be able to give -- does this help
3 you to show the comparison that you were talking about earlier
4 to the folks of the jury?

5 A. It does, yes.

6 Q. All right. This top one is, I believe, the one that you
7 testified was the --

8 A. For the Roche product.

9 Q. Not real.

10 A. Yes.

11 Q. And the bottom one, we have it on your word, it is real.

12 A. Yes.

13 Q. Okay. Go through for us, again, please, the -- I guess
14 you called them the variable data.

15 A. The variable data, yes. You should -- there are --

16 Q. If you can -- and I don't know if you have the ability to
17 point on your screen up there or not but -- that's okay.

18 Okay. I'm sorry I got the terminology wrong. Just
19 by visual examination then, if you could tell us the
20 differences that you see here between the top one, which is
21 not the real one and the bottom one which is the real one.

22 A. Yes. We can start with the writing Tamiflu.

23 Q. Yes.

24 A. On the top you see Tamiflu all on one line.

25 Q. On the top it's all one line.

1 A. Tamiflu, next to it, Tamiflu again, Tamiflu, it's all in
2 one --

3 Q. I see. Okay.

4 A. And on the original below you see Tamiflu, one is up,
5 then Tamiflu is down, then it's up again.

6 Q. Then it's up again. If somebody -- would you agree with
7 me, Doctor, that you have specialized training in being able
8 to tell the difference between what is real and what is not
9 real with respect to the Roche product Tamiflu?

10 A. Yes.

11 Q. All right. If you did not have that training, would you
12 be able to make this determination? If I just covered up what
13 was the real one, would you be able to see the top one was
14 fake?

15 A. Now, I would because I see them every day, original
16 product. But a normal person, I think would not.

17 Q. Would not be able to do it. Okay. Now, we talked about
18 the Tamiflu going up and down. Is there something else about
19 the foil we need to talk about?

20 A. Yes. It's pattern on the top. You see its many small
21 holes. And on the lower one you have, like, lines. But it's
22 easier to see if you have the sample in hand because it's
23 where the foil is, like, pressed in so the lines are pressed
24 into the foil on the lower one and on the upper one it's,
25 like, holes pressed into the foil.

1 Q. That's an incredible subtle difference, isn't it?

2 A. It is different, yeah.

3 Q. I mean, you understand the word "subtle" as in little,
4 hard to see?

5 A. Uh-huh, okay. It is.

6 Q. Hard to see difference?

7 A. Yes.

8 Q. Okay. What else about the foil pack?

9 A. Another difference is the perforated line which we have
10 on the original. The lower one you see the perforations,
11 which makes it easier to divide each single blister pocket
12 from the blister.

13 Q. You're talking about these lines right here -- never
14 mind. You see where the perforation is?

15 A. Yes.

16 Q. Okay.

17 A. You don't see it clear on the upper one. If you have
18 something handed, you see it, but it's not clear at all and
19 it's very light.

20 Q. Okay. Again, that is something that the average everyday
21 person wouldn't notice if they were just taking this product
22 and pulling it out of the pack, they wouldn't say, "Oh, boy,
23 there's perforation here and not a perforation here."

24 A. Yes.

25 Q. You need specialized training for that?

1 A. Yeah, correct.

2 Q. Now, I did that -- we talked then about Government's
3 exhibit -- that was 54. If I ask you the same questions about
4 the foil pack that's in the other Government's exhibits, your
5 answers would be the same with regard to the foil pack and the
6 difference and so forth?

7 A. Yes.

8 Q. Are you taking that sample back with you?

9 A. Yes, I am.

10 Q. Okay. Kind of like to have the real one around so we
11 can --

12 MR. AMANN: Okay. I'll try to figure that out,
13 Judge.

14 BY MR. AMANN:

15 Q. Now, I believe you also stated that in -- Roche did not
16 manufacturer Tamiflu in China.

17 A. Yes.

18 Q. I want to ask you a question or two, if I could, about
19 that. Dr. Nielsen, in December 2005 didn't Roche allow
20 Shanghai Pharmaceuticals in China to manufacture Tamiflu?

21 A. Yes. I'm not sure about the dates. We have given
22 licenses to China for producing Tamiflu but --

23 Q. One of the reasons that you allowed China -- and, as a
24 matter of fact, Vietnam was another country that you allowed
25 to manufacture Tamiflu. One of the reasons you did that is

1 because Tamiflu was designed to combat an outbreak of avian
2 flu, bird flu.

3 A. That's correct.

4 Q. And everybody was concerned that it might become a
5 pandemic. You understand the word "pandemic"?

6 A. Yes.

7 Q. And so Roche allowed china and, in fact, Vietnam to
8 manufacture Tamiflu, didn't they?

9 A. Yes.

10 MR. AMANN: All right. I pass the witness, Your
11 Honor.

12 THE COURT: Any redirect, Mr. Lewis?

13 MR. LEWIS: No, Your Honor. We'll pass the witness.

14 THE COURT: May the witness be excused?

15 MR. LEWIS: Yes, Your Honor.

16 THE COURT: Thank you, Dr. Nielsen, you may be
17 excused.

18 The Government may call its next witness.

19 MR. LEWIS: The United States now calls Dr. Anton
20 Fischer, Your Honor.

21 DR. ANTON FISCHER

22 having been first duly sworn, testified as follows:

23 THE COURT: Be seated, please.

24

25

1 DIRECT EXAMINATION

2 BY MR. LEWIS:

3 Q. Good afternoon, sir. Could you please state your full
4 name and spell your first name and last name for the members
5 of the jury?

6 A. My name is Dr. Anton Josef Fischer, F-i-s-c-h-e-r.

7 Q. And how is your first name spelled?

8 A. Anton?

9 Q. Yes.

10 A. A-n-t-o-n.

11 Q. How are you employed, sir?

12 A. Sir?

13 Q. How are you employed? Where do you work?

14 A. I'm head of QC lab in Roche Baden for control of the
15 laboratory since 2003.

16 Q. Can you explain to the members of the jury your general
17 job duties, your responsibilities?

18 A. We are doing, as the quality control lab, routine
19 released medicines and stability analysis and especially in my
20 function I have an additional lab doing analysis on complaints
21 and counterfeits.

22 Q. Have you had the occasion to examine or analyze few or
23 many suspected counterfeit samples?

24 A. We have many counterfeit samples, especially for Tamiflu,
25 we get about one suspected counterfeit per month.

1 Q. If I can step back for a moment, can you tell us briefly
2 about your education. Where did you attend university?

3 A. I started pharmacy in Wurzburg, Germany and finalized it
4 with a doctorate on pharmaceutical analysis in '88, 1988.

5 Q. And since that time have you worked in the field of
6 chemistry or fields related to chemistry?

7 A. I was a QC head since then in two different companies
8 before I joined Roche in 2003. And there I did also the
9 stability and release testing, and especially since then, my
10 very special knowledge on NIR spectroscopy.

11 Q. Can you, just briefly, spell the name of the city where
12 you earned your Ph.D.?

13 A. It was Wurzburg.

14 Q. And how is that spelled?

15 A. W-u-r-z-b-u-r-g.

16 Q. Do you know Dr. Christin Nielsen?

17 A. Yes.

18 Q. How do you know her?

19 A. She is a colleague of mine in the complaint management of
20 Roche.

21 Q. Did there come a point in time when Dr. Nielsen sent you
22 two samples --

23 A. Yes.

24 Q. -- of suspected counterfeit Tamiflu?

25 A. Yes.

1 Q. And let me show you what's been admitted into evidence as
2 Government's Exhibit No. 54. There are two plastic bags that
3 contain two blister packs of suspected counterfeit Tamiflu.

4 Did Dr. Nielsen send you those two samples to be analyzed?

5 A. Yes.

6 Q. And what year was that?

7 A. This was last year in May.

8 Q. Okay. And what is the first thing you did to perform
9 your test or your analysis of these two samples?

10 A. The first thing that we do, especially in my lab, we do
11 this NIR spectroscopy testing. This is a non-destructive
12 fingerprinting technique. Additionally to the classical, I
13 ask the spectroscopy, that is also a fingerprinting technique,
14 but it's to take out the powder.

15 Q. Please continue.

16 A. Then we additionally did two -- on these samples two
17 chromatography tests. That means one gas chromatography mass
18 spectroscopy analysis and an HPLC which means high performance
19 liquid chromatography test.

20 Q. Thank you. I want to go through those, each of those
21 tests and the purpose of those tests. Before I do that, you
22 mentioned -- or used the term "fingerprinting technique."

23 A. Yes.

24 Q. You were not literally searching for a person's
25 fingerprint or what are you searching for?

1 A. If you have -- if you use spectroscopy, you get
2 absorption bands in this spectrum. And especially for NIR and
3 IR spectroscopy you get very sharp or other bands that are
4 very specific for the specimen that you analyze. So if there
5 are small differences regarding chemical or physical aspects
6 of the sample, compare to the original -- I mean, Roche
7 authentic sample, you would immediately see that. That's why
8 it's accounted for being a fingerprint technique.

9 Q. So it is a -- in a graph or chart form information that
10 you learn from your test that identifies the ingredients or
11 chemical formula for a particular sample; is that correct?

12 A. That's correct.

13 Q. More or less?

14 A. More or less, yes, that's it.

15 Q. Let's talk about the NIR test. What's the purpose of
16 that test? What do you learn from that test?

17 A. The purpose of that test is to get very quickly an NIR
18 image. That means every single pixel of the image we get is
19 one complete NIR spectrum. And we, by comparing those NIR
20 spectra by one image would get 82,000 spectra out of one. And
21 we can do this comparison between the suspect counterfeit in
22 this case and the Roche original sample, the Roche original
23 sample that we are using.

24 Q. Does the NIR test tell you whether the API exists within
25 the tested sample?

1 A. Well, yes, we have -- we are applying specific
2 mathematical statistical procedure with that, chemometric
3 procedure called that we can analyze and tell that a certain
4 extracted information out of this spectrum is related to the
5 API. So we can tell whether the API is in or something is
6 wrong with it.

7 Q. Does the NIR test tell you the amount of the --

8 A. No.

9 Q. -- API that exists within the sample?

10 A. No. We get only a very rough estimation of that. We can
11 tell if this was the case in here that we have not the full
12 amount of API that we have in the Roche sample.

13 Q. Okay. And I want to go through these one at a time
14 because they were tested separately. And let's start with the
15 lowest number sample. It's hard for me to read it upside
16 down.

17 A. 36.

18 Q. Can you read the sample number there?

19 A. This is 36270. This is the complaint number that we take
20 as our reference number throughout this analysis.

21 Q. And with that particular sample, No. 36270, the result of
22 the NIR test, did you find that the API, the active
23 pharmaceutical ingredient was contained in that sample?

24 A. That was, yes, we saw that.

25 Q. And tell us about the IR test, the second test that you

1 performed.

2 A. IR chromatography is usually accompanied with NIR
3 spectroscopy. We get different information out of this region
4 of the spectrum. IR is -- NIR is, beside the visible range
5 and then comes the IR range, so I get different new
6 information about that, also a fingerprinting technique. And
7 here we saw that the API was present. Also we cannot tell the
8 amount. But we saw another aspect, talcum, that isn't a
9 excipient, an additional substance in the powder was not
10 present. And so we saw that also in the NIR image.

11 Q. So in this sample when you performed the second test, the
12 IR test, you found that there was talcum in the sample; is
13 that correct?

14 A. We found no talcum.

15 Q. No talcum.

16 A. Yeah. It should be in the authentic Roche and we saw
17 that it was not inside this. It has a very sharp peak and
18 that was missing.

19 Q. So talcum is ordinarily found in the authentic product,
20 but you did not find it --

21 A. Yes.

22 Q. -- in using the IR test for this particular sample?

23 A. That's right.

24 Q. And tell us what you found -- I'm sorry. Tell us the
25 purpose of the third test, the gas chromatography HPLC test?

1 A. The gas chromatography is performed when we have -- when
2 we see with IR spectroscopy that something is different. And
3 with gas chromatography we find that another excipient, sodium
4 stearyl fumarate, a lubricant, was also missing.

5 Q. Was missing --

6 A. We found --

7 Q. -- from this sample; is that correct?

8 A. Yes, yes. We saw the API also that was given, but this
9 lubricant was missing.

10 Q. And can you say it once again. Then I want you to spell
11 it, the excipient that was missing, stearyl --

12 A. Yeah, stearyl fumarate, s-t-e-a-r-y-l f-u-m-a-r-a-t-e.

13 Q. Okay. So based upon your analysis of this sample, Sample
14 No. 36270, these three tests, the NIR, IR and the gas
15 chromatography test, did you conclude that this sample was
16 counterfeit or authentic?

17 A. We concluded it was counterfeit.

18 Q. And did you prepare a report?

19 A. Yes.

20 Q. Let me show you an excerpt from the report that's been
21 marked for identification purposes as Government Exhibit 54-A.
22 Is this one page from your report?

23 A. This is the complaint, 38120. This is the other case.

24 Q. All right. So if you can hang on to that, I'll come back
25 to that.

1 A. Yeah.

2 Q. Let's talk about the second sample. What is the
3 complaint number for the second sample?

4 A. This is 38120.

5 Q. And did you perform the same three tests on the second
6 sample --

7 A. Yes.

8 Q. -- as you did with the first sample?

9 A. Yes.

10 Q. NIR, IR and gas chromatography test?

11 A. Yes.

12 Q. And let's go through them one at a time. What result did
13 you observe on the second sample when you applied the NIR
14 test?

15 A. We found the same picture. So that this sample was
16 identical, that means we found the same results.

17 Q. Same results. In other words, you found that the active
18 pharmaceutical existed?

19 A. Was present, yes.

20 Q. Was present in the sample. And when you applied the IR
21 test, what did you learn or what did you observe from the
22 results of the IR test when you applied it to the second
23 sample?

24 A. I got this additional report. Can I have a look at that?

25 Q. Sure, if it helps to refresh your recollection.

1 A. Yes, that's it.

2 Q. And what did you observe from the result of the second
3 test on the second sample?

4 A. The excipients were also not in -- were different from
5 the Roche authentic product, but here we found -- and one --
6 substances that are sugars out of the GC and MS tests that we
7 did.

8 Q. Okay.

9 A. And also the absence of this lubricant, stearyl fumarate.

10 Q. The absence of the lubricant, was that the result you
11 learned from the third --

12 A. From the third, yes, yes.

13 Q. -- test, the gas chromatography test?

14 A. Yes.

15 Q. Okay.

16 A. This is the third method.

17 Q. And based upon your application of these three tests,
18 what did you conclude regarding the second sample --

19 A. Also a counterfeit.

20 Q. -- authentic or counterfeit?

21 A. Also a counterfeit.

22 Q. All right. And I handed to you earlier an excerpt from
23 your report for Complaint No. 38120. Is that a copy of one of
24 the pages in your report?

25 A. Yes, that's --

1 Q. And this concerns the second sample that you tested; is
2 that correct?

3 A. That's correct.

4 MR. LEWIS: Government would now offer into evidence,
5 Your Honor, Government's Exhibit No. 54-A. And I'll show it
6 to counsel.

7 MR. AMANN: I have no objection, Your Honor.

8 THE COURT: 54-A is admitted.

9 BY MR. LEWIS:

10 Q. Dr. Fischer, can you tell us, if you know, the amount in
11 milligrams of the API, the active pharmaceutical ingredient,
12 in Tamiflu, how many milligrams?

13 A. Yes, we have 75 milligrams of active substance in each
14 capsule. That corresponds to the salt that is put as a powder
15 into the capsule. That is 98.5 milligrams.

16 Q. And let's go through them one by one. For the first
17 sample, do you know the amount of the active pharmaceutical
18 ingredient, the API that was contained in the first sample?

19 A. That was 74.1 milligram of --

20 Q. So 74.1 milligrams per capsule?

21 A. Per capsule, yes.

22 Q. And what about the second sample, what was the API?

23 A. Oseltamivir phosphate, sorry, the salt that is put in the
24 capsule.

25 Q. Is that the same as the API?

1 A. The API is the powder that you have. But on the package
2 it's labeled 75 milligrams. That is the -- you know, 75
3 milligrams means this is oseltamivir, the name of the API.
4 And if I say 98.5 milligrams of oseltamivir phosphate, this is
5 the substance that you put into the capsule. So this is the
6 same.

7 Q. Okay. What about the second sample, how many milligrams
8 of API were found in the second sample?

9 A. We found 72.9 milligrams of oseltamivir phosphate.

10 Q. If you know, what is the tolerance level for API in
11 Tamiflu?

12 A. We have 100 percent plus or minus 5 percent as the
13 tolerance for release to the market.

14 Q. And what does that mean in your understanding? What does
15 the tolerance level mean?

16 A. That means a hundred percent should be inside the
17 capsule. Due to variances in the production, you are allowed
18 to be within the range of 95 to 105 percent of the claim.
19 This is the normal for each pharmaceutical product on the
20 market.

21 Q. Can you explain to the members of the jury what we're
22 looking at in Government's Exhibit No. 54-A, an excerpt from
23 your report? What is being shown in this picture? Can you
24 see it?

25 A. Yes. What is your question?

1 Q. Yes. The question is -- and I'll rephrase it so I can
2 help out perhaps. Does this picture show both the suspect
3 sample, Complaint No. 38120, and the original authentic
4 product?

5 A. Yes.

6 Q. It does. The suspect sample is on the left and the
7 original is on the right; is that correct?

8 A. Yes. And one reference sample that we take.

9 Q. And there are capsules at the top in the first picture
10 and the bottom picture has what, what's shown --

11 A. This is the powder that is inside the capsule -- that was
12 inside the capsule.

13 Q. So just looking at this picture, they look pretty
14 similar, is that correct, the authentic as well as the sample?

15 A. Pretty similar, yeah, that's true.

16 MR. LEWIS: May I have a moment, Your Honor?

17 THE COURT: Yes.

18 MR. LEWIS: Pass the witness at this time.

19 THE COURT: Thank you.

20 Mr. Amann.

21 MR. AMANN: Thank you, Judge.

22 CROSS-EXAMINATION

23 BY MR. AMANN:

24 Q. Dr. Fischer, good afternoon.

25 A. Good afternoon.

1 Q. My name is Colin Amann. Are you originally from Germany?

2 A. From Germany, yes.

3 Q. I thought I recognized the accent. Are you familiar with
4 how Tamiflu is made, the chemical process by which it is
5 produced?

6 A. No.

7 Q. Okay. Let me -- I'm going to show you something and see
8 if it jiggles any of your memory as a chemist.

9 A. I'm a pharmacist.

10 Q. Pharmacist. Okay. Do pharmacists have to have training
11 in chemistry as well?

12 A. Yes.

13 Q. I'll ask you if you recognize any of the chemical
14 processes involved on this sheet? And if you don't, that's
15 fine.

16 A. Well, as I'm not -- this is not my focus of my
17 profession, you know, we have colleagues that are very good at
18 that.

19 Q. Okay. That's fine. Thank you. Would you agree with me
20 me, sir, that the production, based on your knowledge, that
21 the production of the Tamiflu or -- well I'll restrict it to
22 Tamiflu -- is probably a pretty involved chemical process,
23 there are many steps that must be gone through?

24 A. That's true.

25 Q. And Roche, in fact, has a very elaborate production line

1 where all of these various processes take place; is that
2 right?

3 A. Yeah, that's true.

4 Q. And at the -- and there's a lot of expensive machinery
5 involved in the production of -- let's keep it just with
6 reference to Tamiflu; correct?

7 A. You mean the API substance here or the product?

8 Q. The chemicals, the machines that are used to put the
9 chemicals together, the machines that are used to put the
10 chemicals in the tablets, the machines that are used to put
11 the tablets in the blister packs and the machines that are
12 used to put the blister packs in the packages.

13 A. Okay.

14 Q. First of all, process.

15 A. Yes.

16 Q. Big investment --

17 A. Yes.

18 Q. -- for Roche, lots of money in the development of Tamiflu
19 and marketing of Tamiflu?

20 A. Yes, sir.

21 Q. Now, you talked about that with respect to Tamiflu that
22 you were actually in your complaint division receiving about
23 one complaint a month. Do you remember saying that?

24 A. Yes, yes.

25 Q. So that means that you -- or somebody was submitting a

1 sample to you about once a month and asking you to please
2 examine this or determine whether or not it's real product.

3 A. Yes.

4 Q. Yes?

5 A. Yes.

6 Q. How long has that been going on? How long have you been
7 asked to do this on a once a month basis?

8 A. It started in the end of 2005 that we got our first
9 suspect Tamiflu and all that.

10 Q. Okay. So from 2005 to this good day now, about once a
11 month?

12 A. Once a month.

13 Q. Okay. Now, with respect -- and I'm not going to go in
14 great detail about how the IR machine works and the GC and all
15 of that works. Do you know about how much an IR machine
16 costs?

17 A. Well, around about in dollars 40 to 60,000.

18 Q. And how about a gas chromatography?

19 A. 100,000.

20 Q. How about a mass spectrometer?

21 A. Even more.

22 Q. How about the high performance liquid chromatography?

23 A. 80 to 100,000.

24 Q. And about the NIR machine?

25 A. This imaging machine costs about 250,000 swiss francs,

1 around about the same amount in dollars, yes.

2 Q. So a significant investment to purchase all of these
3 machines and have them in one place and one laboratory at one
4 time; yes?

5 A. Yes, plus don't use one certain machine, not only for one
6 analysis but for many.

7 Q. Sure because you do quality control as well?

8 A. Yes.

9 Q. Because after you produce the product you have to, every
10 now and again, pull one out and make sure it's right?

11 A. Yes.

12 Q. We looked at part of your report, I believe Government's
13 Exhibit 54-A. Do you have your entire report with you?

14 A. I have.

15 Q. May I look at this briefly?

16 A. Sure. This is the other one from 36270. This is a copy
17 of our original.

18 Q. Okay. And this is for the other sample?

19 A. Yes.

20 MR. AMANN: Okay. Thank you very much. Pass the
21 witness, Your Honor.

22 MR. LEWIS: One question, please, Your Honor.

23 REDIRECT EXAMINATION

24 BY MR. LEWIS:

25 Q. Dr. Fischer, if a person or a company wanted to produce

1 counterfeit Tamiflu, they wouldn't need all of the same
2 equipment --

3 A. Yes.

4 Q. -- that Roche has, would they, to produce a counterfeit
5 product?

6 A. Yes.

7 Q. They would not need that expensive equipment; is that
8 correct?

9 A. Yes, that is correct.

10 MR. LEWIS: No further questions. Thank you very
11 much.

12 THE COURT: May the witness be excused.

13 MR. AMANN: Yes, Your Honor.

14 THE COURT: Thank you. Doctor, you're excused.

15 All right. The Government may call its next witness.

16 MR. LOUIS: The Government calls Ed Tarver to the
17 stand.

18 THE COURT: Please come around and be sworn as a
19 witness.

20 ED TARVER

21 having been first duly sworn, testified as follows:

22 THE COURT: Be seated, please.

23 Mr. Louis, you may proceed.

24 MR. LOUIS: Thank you, Your Honor.

25

1 DIRECT EXAMINATION

2 BY MR. LOUIS:

3 Q. Please state your name and spell your last name for the
4 benefit of the jury and the court reporter.

5 A. Edward Tarver. That's T-a-r-v-e-r.

6 Q. How are you employed, Mr. Tarver?

7 A. I'm special agent with the U.S. Immigration and Customs
8 Enforcement.

9 Q. Is that known as ICE?

10 A. ICE, yes, sir.

11 Q. And where are you assigned within the Immigration and
12 Customs Enforcement?

13 A. Houston, Texas.

14 Q. Are you assigned to a specific division or squad?

15 A. Yes, sir, I am.

16 Q. And what is that?

17 A. I'm assigned to the investigation unit that investigates
18 counterfeit pharmaceuticals and commercial fraud.

19 Q. How long have you been assigned to that particular
20 unit?

21 A. Approximately ten years.

22 Q. And how many total years of experience do you have
23 working with Immigration and Customs Enforcement?

24 A. I've got 37 years.

25 Q. Prior to working for the -- your 37-year tenure with ICE,

1 did you have any other law enforcement experience?

2 A. Total I have 16 years with the Louisiana state police as
3 detective and 22 years with ICE, 37 altogether, 38.

4 Q. 37, 38 years in law enforcement?

5 A. Yes.

6 Q. Do you have an occasion assigned to a commercial fraud
7 group to participate in investigations concerning the
8 counterfeiting of commercial products?

9 A. Yes, sir, I do.

10 Q. Does that include pharmaceutical products?

11 A. Yes, sir, it does.

12 Q. And did you have an occasion to be involved in
13 investigation of the defendant, Mr. Kevin Xu?

14 A. Yes, sir, I did.

15 Q. And what role did you play in this investigation?

16 A. I was the -- I'm the program manager for the
17 investigative unit, which means I direct investigations and
18 come up with investigative strategies to use in investigations
19 and assist agents in their investigations, both in
20 interrogation and investigations.

21 Q. All right. With respect to this case, did you have an
22 occasion to -- after obtaining all the -- were you involved in
23 the obtaining of any pharmaceutical drugs that were sent to
24 either a drop box or a mailbox drop utilized by the
25 Immigration and Customs Enforcement?

1 A. Yes, sir, I was.

2 Q. And did you assist in sending any pharmaceutical products
3 off to the labs?

4 A. Yes, sir, I did.

5 Q. In addition, did you have an occasion to figure out or
6 contact individuals to find out what the average wholesale
7 price of the drugs at issue?

8 A. Yes, sir, I did.

9 Q. The drugs at issue in this case are what?

10 A. It's Plavix, which is for heart disease, Zyprexa, which
11 is for dementia, Casodex, which is a cancer drug, Aricept,
12 which is for Alzheimer's disease and Plavix -- Zyprexa, which
13 is for -- Tamiflu, I'm sorry, Tamiflu was the other one.
14 Tamiflu, which is for bird or avian flu.

15 Q. All right. Let me show you what's already been marked
16 and admitted into evidence as Government's Exhibit 57. Now,
17 this is a chart that was prepared by another agent within your
18 unit, Corbin Wickman?

19 A. Yes, sir, it was.

20 Q. And this particular chart has the price that was paid to
21 Mr. Kevin Xu for the various pharmaceutical drugs; is that
22 right?

23 A. That's correct, sir.

24 Q. There were two purchases of various pharmaceutical drugs.
25 Can you see that?

1 A. Yes, sir.

2 Q. Let me give you the original. It's here somewhere.

3 Looking at -- can you see that?

4 A. Yes, sir, I can see it.

5 Q. Have you had to -- this has the retail price; is that
6 right?

7 A. That's correct.

8 Q. Were you able to find out what the average wholesale
9 price was?

10 A. Yes, sir, I was.

11 Q. And for the record, what is the average wholesale price?
12 What does that term mean?

13 A. It's a wholesale acquisition cost. That's the cost that
14 a distributor would have to pay for the pharmaceutical and
15 then tack on his own cost in order to sell it to the consumer.

16 Q. Who did you consult to find out what the wholesale
17 acquisition cost would be?

18 A. We consulted the pharmaceutical companies that
19 manufacture the drug.

20 Q. So now, let's take the first line that we have here, I
21 think it's Tamiflu.

22 A. Yes, sir.

23 Q. Come all the way across, Tamiflu, 100 boxes, there were
24 seven tablets per box and the average retail price is \$10.71.
25 Do you see that?

1 A. Yes, sir.

2 Q. Now, the price that we -- that was paid to Mr. Xu is
3 \$2.20; is that right?

4 A. \$2.20.

5 Q. What is the average wholesale price, then, for a tablet
6 of -- this is per tablet; is that right?

7 A. That's correct. And actually those are closer to the
8 wholesale figures. He got the wrong value up there. But the
9 average wholesale is going to be somewhere around -- I'm
10 sorry.

11 MR. AMANN: Pardon me, sir, I don't mean to interrupt
12 you.

13 With respect to what somebody else told him about
14 what wholesale prices may have been, Your Honor, I think that
15 is a hearsay statement and I would object to it.

16 THE COURT: Sounds like hearsay to me, Mr. Louis.
17 BY MR. LOUIS:

18 Q. Did you yourself make a determination as to what the
19 wholesale price was?

20 A. I contacted the pharmaceutical companies to get the
21 wholesale price that they were charging to their customers.

22 Q. All right. And have you in the connection with your
23 investigations done it on many occasions?

24 A. I've done it on almost every case, sir.

25 MR. LOUIS: Your Honor, this chart has already been

1 admitted into evidence. This is for purposes of
2 clarification. It is not offered for additional purposes.
3 It's offered simply to clarify information that's a part --

4 THE COURT: Sounds to me like it's offered for the
5 truth of the matter asserted, which would make it, by
6 definition hearsay.

7 MR. LOUIS: Well, I will ask it in this regard.

8 BY MR. LOUIS:

9 Q. With respect to the figures that are in evidence, is the
10 wholesale price higher or lower?

11 MR. AMANN: Your Honor, that asks for information
12 that is based on hearsay.

13 THE COURT: I sustain the objection.

14 MR. LOUIS: All right.

15 BY MR. LOUIS:

16 Q. Well, let's look at this chart. This chart has the
17 retail value?

18 A. That's actually closer to the wholesale value.

19 MR. AMANN: Your Honor, he's testifying to hearsay.
20 I object to it and ask the Court to instruct the jury to
21 disregard what he just said.

22 THE COURT: All right. The jury will disregard the
23 last answer.

24 BY MR. LOUIS:

25 Q. The price that you paid, based on this chart, the price

1 that you paid Mr. Xu, is that significantly lower than the
2 retail price that's listed here?

3 A. It's much significantly lower, sir.

4 Q. And that's for the Tamiflu. Let's quickly go Zyprexa.

5 THE COURT: We've already covered this and the
6 exhibit speaks for itself. We've covered this with another
7 witness.

8 MR. LOUIS: Yes, sir.

9 BY MR. LOUIS:

10 Q. Lastly, did you have an occasion to obtain information
11 about the email account from Mr. Xu?

12 A. Yes, I did.

13 Q. And who did you contact to obtain that information?

14 A. I contacted the internet service provider for Mr. Xu,
15 the -- or the account holder for Mr. Xu's internet account.

16 Q. And for what purpose did you do that?

17 A. To determine who the account's registered to and where
18 the IP address is which allowed us to determine where the
19 conversations were originating.

20 Q. And let me show you Government's Exhibit No. 1. Is that
21 information that you received back from the service provider?

22 A. Yes, sir, it is.

23 Q. And then looking at what's been marked and admitted as
24 Government's Exhibit No. 13, is that the same email account
25 that you were provided information on?

1 A. Yes, sir, it is.

2 MR. LOUIS: Pass the witness.

3 MR. AMANN: May I approach very quickly, Your Honor?

4 THE COURT: Yes.

5 MR. AMANN: I meant the witness. Sorry.

6 I have no questions, Your Honor.

7 Wait, wait. I'm sorry. Somebody's yelling at me.

8 Actually may I borrow your --

9 MR. LOUIS: You want to offer it?

10 MR. AMANN: No, I'm just going to ask him a couple of
11 questions from it and I want to have it handy.

12 May I approach the witness again, Your Honor?

13 THE COURT: Yes.

14 CROSS-EXAMINATION

15 By MR. AMANN:

16 Q. Agent Tarver, good afternoon.

17 A. Yes, sir. How are you doing?

18 Q. Tired. Now, when you were trying to figure out -- I
19 guess an IP address is internet provider address; correct?

20 A. That's my understanding, yes, sir.

21 Q. Okay. And the internet provider address is -- can be
22 established to many different places; right?

23 A. That's my understanding.

24 Q. I mean, an internet provider address can be -- it can
25 come from a Starbucks, it could come from a Denny's, it could

1 come from just anywhere; right?

2 A. That's my understanding.

3 Q. Okay. And what you need to do is each computer has a
4 little -- I think they call it a mac device in the computer
5 that makes -- creates some kind of signature so that based on
6 the IP address you can go back and check that IP address and
7 match it to the mac address?

8 A. I don't know. All I can tell you is that we have some
9 agents who are trained in that. And we give them the
10 information and then they can give us the information back.

11 Q. Okay. So you're as -- about computer savvy as I am then.

12 A. I wish I could tell you I knew more, but all I can tell
13 you is I give information to them and they give me the
14 information back.

15 Q. All right. That's fine.

16 MR. AMANN: Thank you, Your Honor. I pass the
17 witness.

18 MR. LOUIS: No questions.

19 THE COURT: Thank you, Mr. Tarver. You're excused.

20 THE WITNESS: Thank you, sir.

21 MR. LOUIS: Your Honor, the Government would rest at
22 this time.

23 THE COURT: All right. Do you have a witness
24 available for this afternoon?

25 MR. AMANN: Not until tomorrow morning, Your Honor.

1 THE COURT: All right. We're moving along pretty
2 quickly. So it may be that the case will be presented to you
3 tomorrow. We don't know for sure. But, again, thank you for
4 being here promptly this morning. We're going to adjourn a
5 little bit early. We'll reconvene again at 8:30 tomorrow
6 morning. I remind you again, do not discuss the case with
7 anyone or allow anyone to discuss the case with you. Do not
8 read or listen to any mention of the case in the media and do
9 not do any independent investigation or research. I'll see
10 you bright and early at 8:30 tomorrow morning. Thank you.

11 (Outside the presence of the jury.)

12 THE COURT: Be seated please.

13 All right. The Government having rested --

14 First of all, I need to put on the record that one of
15 the jurors handed the bailiff a note at 12:56 saying,
16 "translator for Mr. Xu is distracting, overrides audio and
17 sometimes witnesses." I informed counsel outside the presence
18 of the court reporter earlier. I just want to put this on the
19 record.

20 All right. Government having rested, the defense may
21 now make any motion.

22 MR. AMANN: Judge, briefly, under Rule 29 we would
23 ask this Court to consider instructing a judgment of
24 acquittal. And my major point on that is that the Government
25 is required to prove by the elements of the offense and by the

1 allegations contained in the indictment that these various
2 drugs, Zyprexa, the Plavix, and the Court is very familiar
3 with all the drugs, have been trade market -- trademarked, I'm
4 sorry, registered and patents are currently on file, have not
5 expired and that is an element of the offense. The Government
6 has rested. We've not heard word one about any of these
7 products being trademarked, about whether the patents are
8 still alive, whether they've lapsed. We just don't know. And
9 that's an element of the offense and the Government has not
10 even attempted to prove that.

11 THE COURT: What's the Government's response?

12 MR. LOUIS: The Government's response is we've called
13 a witness from every trademark holder except Casodex. And we
14 have established from the trademark holder that the products
15 that Mr. Xu provided to the undercover agent were trademark
16 products, they were not the authentic product, they traveled
17 through interstate commerce.

18 THE COURT: Well, Mr. Vernon Lewis established that
19 for Roche. I don't recall that you asked any of the other
20 chemists or pharmaceutical manufacturer representatives about
21 trademarks or other forms of intellectual protection.

22 MR. LOUIS: I asked -- the first witness we called
23 was from -- Amy Callanan, I asked her if she compared the
24 suspect sample with the trademark with the reference sample,
25 with the trademark sample. She said they did that and that

1 the sample was counterfeit. I asked that question to each and
2 every chemist from every pharmaceutical company and especially
3 with the last witness, Michael Dalton, specifically is this
4 product, Zyprexa, a product that is trademarked by Lilly. I
5 have the actual excerpt from the report. And I asked him to
6 compare the product reference sample from the legitimate
7 product, authentic product to the counterfeit suspect sample.
8 And each and every time the answer was that this product was
9 not the authentic product of the trademark.

10 MR. AMANN: Your Honor, may I briefly respond?

11 THE COURT: All right.

12 Well, also, the exhibits offered by the Government
13 for some of the legitimate products have the simple "TM" or
14 "R" by them. And they have that symbol by all of the
15 counterfeit products. I don't know whether that is sufficient
16 to establish that element or not.

17 MR. LOUIS: It's the Government's contention that it
18 is. The Government does not have to have the actual date and
19 time. The question would be whether or not the trademark
20 holders were called to testify that this is a registered --
21 that this is a product, authentic product or not authentic
22 product. We established that.

23 THE COURT: I didn't recall each of your witnesses
24 testifying to that. I know the Roche -- one of the Roche
25 representatives did.

1 Go ahead.

2 MR. AMANN: Your Honor, in the indictment if we just
3 look at Counts 5 through 9 -- let's use 5 as an example.
4 They're talking about Eli Lilly and that the mark on the
5 alleged counterfeit was substantially indistinguishable from
6 the genuine mark and registered for that good on the principal
7 register in the United States Patent and Trademark Office.
8 That is an element of the offense because trademarks expire.
9 Every so often they expire. They need to be reviewed. For
10 the offense in question, we're talking about the years from
11 July 2006 through July 2007 or thereabouts. There has to be
12 proof from the U.S. Patent Office, via by some authentic
13 certified document or something of that nature that these
14 patent trademarks were alive in effect and applicable.

15 THE COURT: Well, that might -- first of all, I'm not
16 persuaded that the Government has failed with respect to all
17 of the products. Certainly not with respect to Tamiflu.

18 Moreover, the Counts 2, 3 and 4 don't require
19 registration, they just require misbranding.

20 Count 1, there could be a conspiracy misbrand without
21 a conspiracy to introduce counterfeit prescription drugs. So
22 I'm going to deny your motion. If the jury finds a verdict of
23 guilty, you can file a motion supported by legal authority
24 then and I'll give it more careful consideration.

25 You can respond then.

1 And by then we'll have a transcript of the record
2 which should inform our discussion and my analysis.

3 MR. AMANN: Yes, sir. And as part of the Rule 29
4 motion, I would make the argument that based on the evidence
5 we have before us, that no rational juror could find beyond
6 all reasonable doubt that Mr. Kevin Xu knew that these items
7 were counterfeit. I believe the proof is lacking in that
8 regard. The Court has been taking copious notes throughout
9 the course of the trial, I don't need to belabor the reasons.
10 The reasons from my standpoint are fairly obvious. They
11 didn't prove he had a factory, they didn't prove he was a
12 manufacturer. They took no steps to try to ascertain that. I
13 just don't think there's enough evidence to prove beyond a
14 reasonable doubt to the extent that a rational juror could
15 find Mr. Xu guilty.

16 THE COURT: Well, there's ample evidence that his
17 knowledge and mens rea objection has no merit.

18 All right. What we do need -- have y'all looked at
19 the charge?

20 MR. LOUIS: I have.

21 THE COURT: We're going to take a short recess.
22 Also, we probably ought to submit for the verdict form for
23 Count 1 -- we ought to give the jury a chance to find a
24 conspiracy to violate either 3320(a) or 33 -- or 21 USC 331(a)
25 or (i). Is there an instruction on 331(a)?

1 MR. LOUIS: Your Honor --

2 THE COURT: I tell you what, let's just take a
3 ten-minute recess. I want to talk about that issue and then
4 I'll entertain the defendant's objections. Take a ten-minute
5 recess.

6 We'll need the defendant here for this.

7 THE MARSHAL: Yes, Your Honor.

8 (A recess was taken.)

9 THE COURT: Please be seated.

10 First, I'll hear objections by counsel to the charge
11 that I've given you at the noon recess.

12 Does the Government have any objections?

13 MR. LOUIS: The Government has no objections.

14 THE COURT: All right. Let's hear from the
15 defendant. What, if any, objections does the defendant have?

16 MR. AMANN: Judge, I have a few referring to the
17 Court's charge. On Page 6 of the Court's charge, we have in
18 the second full paragraph beginning, "You are the sole judges
19 of the credibility," the second sentence, "An important part
20 of your job will be making judgments about the testimony of
21 witnesses[including the defendant.]" Mr. Xu is not going to
22 testify. I'd like to have that excluded.

23 THE COURT: I'll exclude that and I'll exclude the
24 language on the next page also.

25 MR. AMANN: Yes, sir.

1 THE COURT: I have it in there because you hadn't
2 made your election yet. Okay. Thank you.

3 MR. AMANN: Judge, moving to Page 12 of the charge
4 concerning certain chart summaries and the like, I don't know
5 that those are in play here. If they are, I just don't --

6 MR. LOUIS: I had one that I was going to offer, but
7 I did not so --

8 THE COURT: Okay. Well, that's good. The less I
9 have to read, the better.

10 MR. AMANN: Okay. With respect on Page 13 the
11 definition of "knowingly," the second full paragraph beginning
12 with, "You may find the defendant had knowledge," that whole
13 paragraph, I believe, relates to deliberate ignorance. I
14 think the deliberate ignorance charge should be used very
15 sparingly. I don't believe it's warranted in this case and I
16 would object to its inclusion in the Court's charge.

17 THE COURT: Well, it's clearly supported by this case
18 for a number of reasons. I noted the most blatant evidence
19 supporting it would be Mr. Xu's testimony on July 1 in which
20 he stated on the tape words to the effect of coaching
21 Mr. Sherman about how to disclaim knowledge concerning the
22 branding of the pills. There's another reference where they
23 had a discussion about the fact that even if the treatment for
24 cancer didn't work, it wouldn't necessarily prove that the
25 drug was counterfeit because the oncologist might then just

1 prescribe another drug for the same treatment. There's
2 evidence of willful blindness here so that objection is
3 overruled.

4 MR. AMANN: Thank you, Your Honor.

5 Moving along, trying to see what pages I have dog
6 eared here, moving along to Page No. 23, this regards
7 trafficking in counterfeit goods. We had requested the Court
8 to submit in our requested instructions a fifth element to the
9 effect that the use of the counterfeit mark was likely to
10 cause confusion, to cause mistake or to deceive. It's my
11 understanding that the Court is going to deny that request.

12 THE COURT: I am. I looked at the Fifth Circuit
13 authority, which the Government submitted beginning with
14 United States versus Salton, 115 F.3d 321, which uses the
15 exact language both as to elements of the offense and
16 definitions submitted by the Government. *Salton* was approved
17 by the Fifth Circuit in United States versus *Hanafy*,
18 H-a-n-a-f-y, 302 F.3d 485, which actually cites *Salton*. And
19 in a later case, *United States versus Zheng Yi* 460 F.3d 623.
20 I asked my law clerk to research it and we searched every
21 circuit in the United States and have not found one circuit
22 that includes your fifth element. So I'm going to go along
23 with the Fifth Circuit.

24 MR. AMANN: All right. And just so the record is
25 clear because I don't know if our previous discussion was

1 actually on the record, I requested it simply because the
2 Government had alleged as an element in the relevant counts of
3 the indictment so, therefore, I thought it was incumbent upon
4 them to prove it.

5 THE COURT: Of course, the jury will see the
6 indictment but the jury will be instructed that what the
7 Government has to prove is what is contained in these
8 instructions. Furthermore, your fifth element about likely
9 confusion seems to me to be covered by the definition of
10 counterfeit mark, which is included in the Court's
11 instructions.

12 MR. AMANN: I understand that. I'm sorry. The
13 Court's overruling that particular objection?

14 THE COURT: The Court's overruling both of your
15 objections to the instructions on Counts 5 through 9.

16 MR. AMANN: With respect to the definition of
17 counterfeit mark, in my requested instructions I submitted a
18 verbatim recitation of what counterfeit mark means taken right
19 from the statute itself. It's my -- looking at the Court's
20 charge, the counterfeit mark on Page 23, the last sentence
21 from the end is, according to this charge, "spurious mark used
22 in connection with trafficking," et cetera, et cetera. The
23 Court can certainly read that. I think that the counterfeit
24 mark definition should be the three elements of the definition
25 which are conjunctive in nature, should be as set forth in my

1 requested charge, it's defendant's requested Jury Instruction
2 No. 7 that has been filed. It's right out of the statute,
3 Your Honor, it is conjunctive so, therefore, I think all three
4 parts of that definition should be set forth to the jury.

5 THE COURT: I'm going to overrule that objection.

6 MR. AMANN: And --

7 THE COURT: The lesser included instruction is the
8 one you requested.

9 MR. AMANN: Yes, sir. And I believe that's been
10 included in the Court's charge. And I believe -- I haven't
11 actually made it to the verdict form yet, but I'm there right
12 now. I don't know that it's been included in the Court's
13 charge, the requested verdict form that we submitted with
14 respect to the lesser included.

15 THE COURT: Question what? It's in there?

16 MR. AMANN: Is it? I'm sorry.

17 THE COURT: It should be.

18 MR. LOUIS: It is.

19 THE COURT: Look at Page -- bottom of Page 1 of the
20 verdict form.

21 MR. AMANN: Okay.

22 MR. LOUIS: Also Page 21.

23 MR. AMANN: I'm sorry. I just read the top part. I
24 was going quickly, Your Honor.

25 THE COURT: I know. It's been a busy day.

1 MR. AMANN: That concludes our objections, Your
2 Honor.

3 THE COURT: All right. Now, since the defense has
4 raised a colorable objection to one of the elements of one of
5 the crimes. I think what we need to do is provide a different
6 verdict form for Count 1, which asks whether the jury finds
7 the conspiracy to traffic or attempt to traffic in counterfeit
8 goods in violation of 2320(a) or alternatively (b) or (c); in
9 other words, I want three verdict forms for Count 1 so if, in
10 fact, you lose on the 2320(a) substantive offenses, the
11 conspiracy could still be found based on conspiracy to violate
12 a statute other than 2320(a). Do you understand?

13 MR. LOUIS: Yes, I was going to say, I just realized
14 there's not a unanimity instruction in here, is there.

15 THE COURT: No.

16 MR. LOUIS: All right. I would -- the Government
17 would recommend putting one in. I had one in the previous
18 case. I just don't have it with me. It just dawned on me
19 when the Court said that -- I have no objection to a unanimity
20 instruction. That's cures that.

21 THE COURT: That doesn't cure that. I've got the
22 same problem in the Enron case. There were 50 pages of
23 briefing on that.

24 MR. LOUIS: Okay.

25 THE COURT: So I'd rather not have it in this case.

1 MR. AMANN: May I coattail all that briefing?

2 THE COURT: No, I don't think -- we're not
3 submitting --

4 MR. AMANN: Okay.

5 THE COURT: -- the alleged instruction -- the
6 instruction, two judges of the Fifth Circuit have found
7 inappropriate. But we do need -- what is a 331(a) violation?

8 MR. LOUIS: 331(a) is the introduction into
9 interstate commerce of a product that's been misbranded. And
10 the second one, 331(i) is introduction -- is a product that is
11 counterfeit.

12 THE COURT: All right.

13 MR. LOUIS: And that's set forth in the indictment,
14 three ways in which a conspiracy --

15 THE COURT: Okay. The jury is told later on about
16 misbranded drugs. What if the jury comes back and says, "How
17 do we know whether there's a conspiracy to violate 331(i)?
18 You haven't given us a definition of the elements of 331(i)
19 violation." You understand my concern?

20 MR. LOUIS: Yes.

21 THE COURT: You haven't alleged a 331(i) substantive
22 violation, but you've alleged a conspiracy to violate it. So
23 I need some instruction of what would be required.

24 MR. LOUIS: I want to say let's just take it out.

25 THE COURT: Pardon me?

1 MR. LOUIS: Let's just take it out. Really there is
2 very little evidence at this point. The evidence that -- so
3 if it's a question of how to instruct the jury on that, I do
4 have something I can look at if the Court gives me about ten
5 minutes.

6 THE COURT: No. What I want you to do is you get the
7 definition or the instruction you want for 331(i).

8 MR. LOUIS: I have it.

9 THE COURT: And then you get the proposed verdict
10 form for Count 1. You fax them to opposing counsel. Y'all
11 either agree -- by 8:20 tomorrow let me have your respective
12 submissions and some law that makes your submission superior
13 to your opponent's. It's not helpful for me to discuss it in
14 general. It would be more helpful for me to see the precise
15 language.

16 MR. LOUIS: I've got it. It's just in a different
17 case. I'll go pull it and I'll send him that information.

18 THE COURT: And y'all talk about it. You don't have
19 to -- I want you to talk before you file tomorrow.

20 MR. AMANN: We talk quite a lot, Your Honor.

21 THE COURT: Okay. Good. Let's -- you're also going
22 to give me an exhibit list, which includes all these --

23 MR. LOUIS: I had it and I looked at it before I
24 handed it to the Court and there is a couple of typos. So I'm
25 going to go down and fix that and I'll bring it to your law

1 clerks in a few minutes.

2 THE COURT: Okay. And we'll cover that -- let me
3 just cover what is in evidence now, other than that, so we can
4 save some time tomorrow.

5 Exhibit keepers, turn to your notes, please.

6 MR. AMANN: I'll call for my substitutes for that,
7 Your Honor.

8 THE COURT: Okay. We'll go through the pages. There
9 are no defense exhibits in evidence at this point. We'll go
10 to the pages.

11 On Page 1, Government's Exhibits 2, 3, 3-A, 4, 4-A,
12 5, 5-A, 6, 7, 7-A, 8, 9 and 9-A are in evidence.

13 Any disagreement?

14 MS. KETTERMAN: No, sir.

15 THE COURT: Page 2, all the exhibits except 11 are in
16 evidence.

17 MS. KETTERMAN: I agree.

18 THE COURT: Page 3, all of the exhibits are in
19 evidence.

20 MS. KETTERMAN: I agree.

21 THE COURT: Page 4, Exhibits 37 through 44 are
22 admitted. 45 and 46 were not admitted. 47 through 50-A were
23 not offered. And 51 and various subparts to be identified
24 were admitted. Does defense agree?

25 MS. KETTERMAN: I agree, Your Honor.

1 THE COURT: Page 5, 52, 52-A, 53, 53-A, 54 and 54-A
2 were admitted. 56 and various subparts to be identified were
3 admitted. 57 was admitted. Government's Exhibit 60, Pages 1,
4 2, 4, 5, 6, 14, 15, 16, 18 and 26 were admitted. Pages 17 and
5 27 were not admitted. No others were offered. Then
6 Government Exhibit 61 and 62 were admitted.

7 Are we all in harmony on that?

8 MS. KETTERMAN: Yes, sir.

9 MR. LOUIS: Yes.

10 THE COURT: Okay. How long will your character
11 witness take?

12 MR. AMANN: Judge, he is -- I don't know, less than
13 an hour.

14 THE COURT: All right. Then we'll probably argue in
15 the morning. Does anybody need more than 30 minutes?

16 MR. AMANN: I might need 30 minutes just to walk back
17 and forth on all the exhibits.

18 MR. LOUIS: 35.

19 THE COURT: You know if I said an hour and 30, you
20 would want an hour and 40.

21 MR. LOUIS: Just in my mind thinking this is why I --
22 one of the times I had a trial and the Court gave me 30
23 minutes and I ended up taking 26 minutes and I looked around
24 and I remember co-counsel had about four minutes left. So
25 that's why I said 35.

1 THE COURT: I think we can get by -- if you're still
2 going with 30 and you need a minute or two, just ask me.

3 MR. LOUIS: All right.

4 THE COURT: 30 minutes.

5 MR. LOUIS: You'll probably throw something at me if
6 I take that time.

7 THE COURT: You know, I had that experience arguing
8 before the Texas Supreme Court. We divided up the argument.
9 My co-counsel took all the time, he got reversed and I got
10 reversed too because I didn't have a chance to distinguish my
11 case. So what I learned, next time I'm going first. So
12 Mr. Lewis gets to go first tomorrow.

13 MR. LOUIS: If the court orders it.

14 THE COURT: I didn't say which Mr. Lewis.

15 Okay. So, anyway, that's what we'll do tomorrow.

16 I'd really like to get -- I hope you can agree on these
17 instructions because I would like to get -- I've got to get
18 this revised and typed in the morning.

19 Okay. We'll stand in recess until tomorrow morning.

20 (Court recessed at 4:37 p.m.)

21

22 I certify that the foregoing is a correct transcript
23 from the record of the proceedings in the above-entitled
24 matter.

24

25

/s/

JEANETTE BYERS, RPR
September 3, 2008